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TEFCA Update to the Health IT Advisory Committee

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- TEFCA overview
- What are the components of TEFCA?
- What are the Exchange Purposes under TEFCA and how do they work?
- What privacy and security requirements are included in TEFCA?
- How do you become a QHIN?
- How will TEFCA be operationalized?
- Questions & Answers



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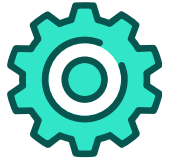
TEFCA overview



*“[T]he National Coordinator shall convene appropriate public and private stakeholders to **develop or support a trusted exchange framework** for trust policies and practice and for a **common agreement** for exchange between health information networks.”*

[emphasis added]





GOAL 1

Establish a universal policy and technical floor for nationwide interoperability



GOAL 2

Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value



GOAL 3

Enable individuals to gather their health care information



Relevant, trusted information from nationwide sources for:



Individuals

Use an app to access their own records from TEFCA-connected sources located across the nation.



Providers and Health Systems

Improve care, coordination and population health by obtaining a more informed picture of care across settings through fewer connection points.



Public Health

Improve quality, reduce costs, and expand public health interoperability.



Payers

Get and share data needed for care management, value-based care, payer-to-payer exchange, etc.



Health Information Networks

Enhance the value of network participation and lower the cost of connecting with other networks.



Technology Developers

Provide a scalable policy and technical ecosystem for innovation.

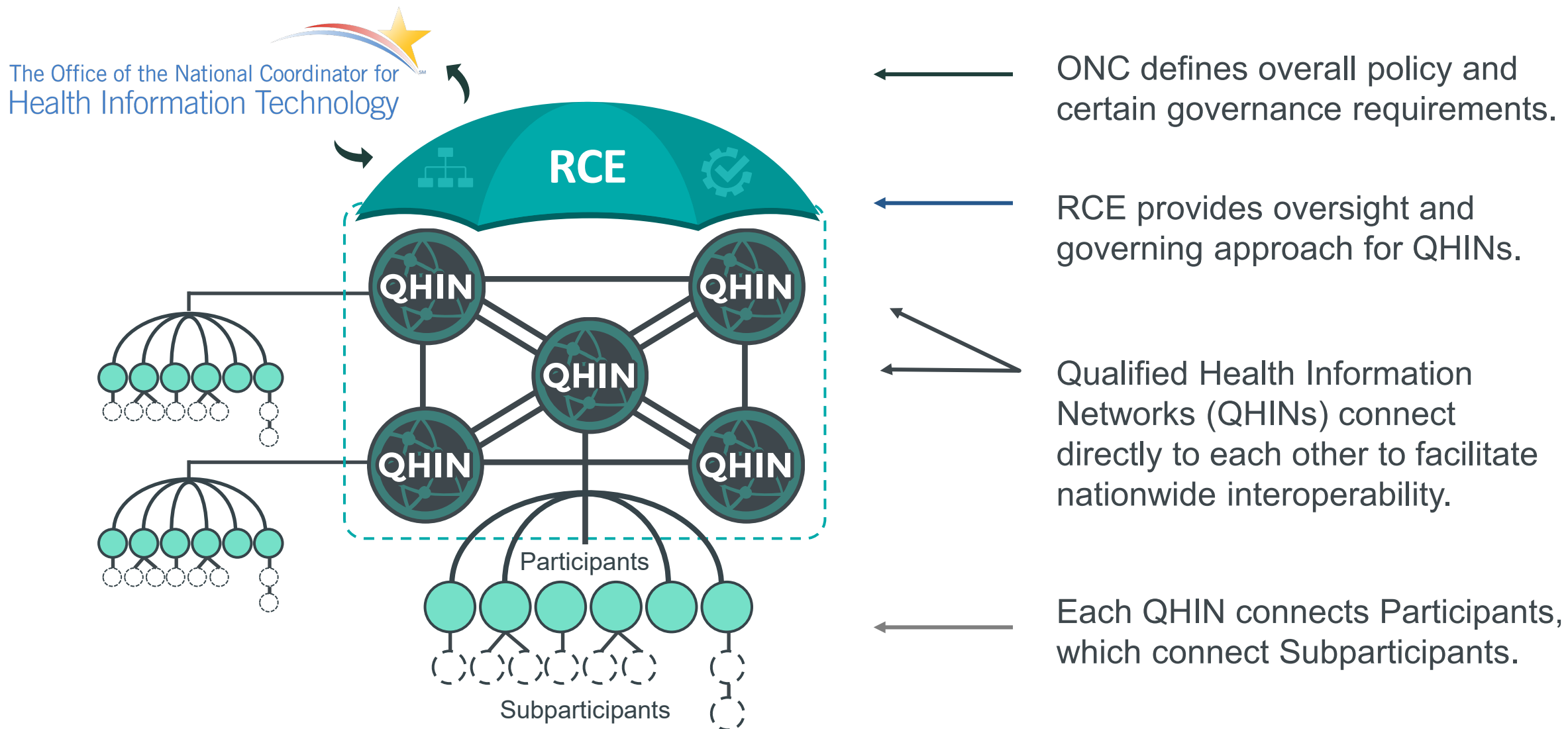


Researchers (Future)

Improve quality, reduce costs, and expand participation in clinical research.

For more detail on the benefits of TEFCA for stakeholders, see factsheets at: <https://rce.sequoiaproject.org/tefca-and-rce-resources/>

How will exchange work under TEFCA?





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What are the components of TEFCA?

TEFCA Components



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Trusted
Exchange
Framework

**Released
Today**



Common
Agreement

**Released
Today**



Standard
Operating
Procedures

**7 SOPs
Released
Today**



QHIN
Technical
Framework

**Released
Today**



QHIN
Onboarding

**Released
Today**



Metrics



Governing
Approach

Materials at: <https://rce.sequoiaproject.org/tefca-and-rce-resources/> and <https://www.healthit.gov/tefca>.



The **TEF** describes a common set of non-binding, foundational principles for policies and practices to facilitate data sharing among health information networks.

Broad industry alignment with these principles can help entities enter into more uniform contractual relationships that are required for improved electronic flow of health information where and when it is needed.

The TEF includes seven principles:

Standardization

Openness and Transparency

Cooperation and
Non-Discrimination

Privacy, Security, and Safety

Access

Equity

Public Health



- The **Common Agreement** establishes the infrastructure model and governing approach for users in different health information networks to securely share clinical information with each other.
- The Common Agreement is a legal contract that both the RCE signs and a health information network (or other entity) signs.
 - » The latter becomes a Qualified Health Information Network (QHIN) once fully onboarded and designated by the RCE.
- Some provisions of the Common Agreement will flow down to entities in a QHIN's network via other agreements.
- The Common Agreement incorporates the QHIN Technical Framework and the Standard Operating Procedures (SOPs).



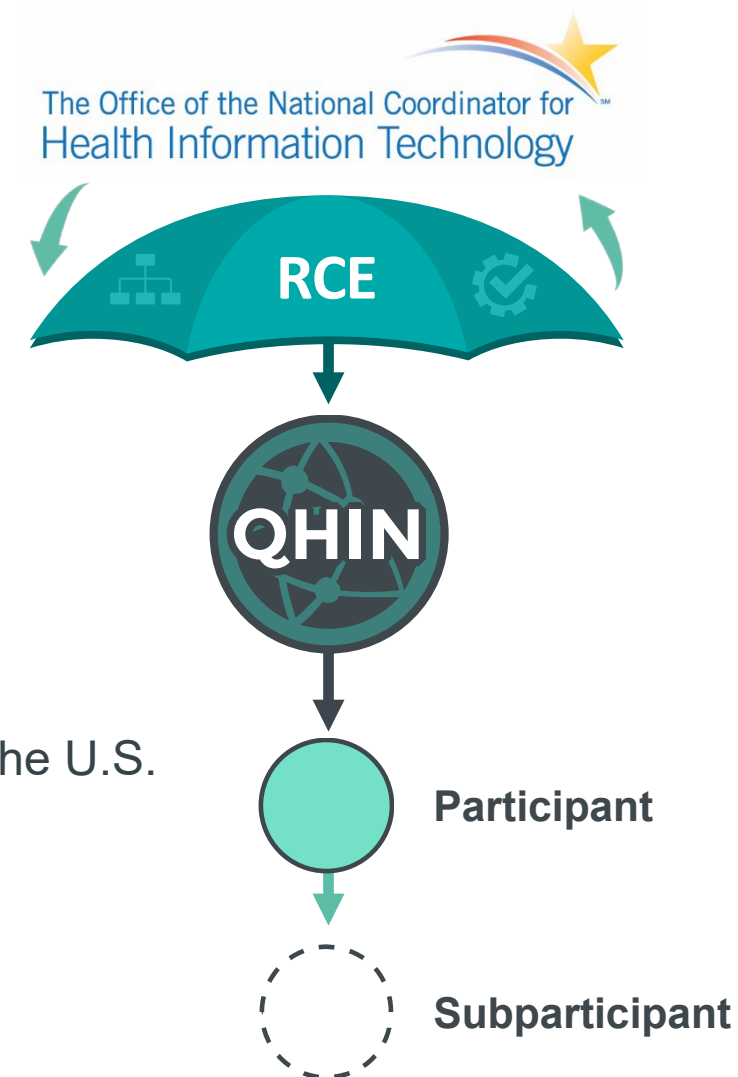
Common Agreement

Each QHIN shall voluntarily enter into a contractual agreement with the RCE by signing the Common Agreement, making all QHINs parties to the Common Agreement. The Common Agreement includes flow-down clauses for the QHIN's agreements with its Participants and each Participant's agreements with its Subparticipants.

Required Flow-Downs Will Address:

- Cooperation and Nondiscrimination
- Confidentiality
- Utilization of the RCE Directory Service
- Uses, Disclosures, and Responses
- Individual Access Services
- Privacy
- Security
- Special Legal Requirements
- TEFCA Information Outside the U.S.
- Other General Obligations

Entities may connect into exchange at any level, but must abide by the flow-down provisions, which create common “rules of the road.”





The RCE has developed SOPs on topics such as:

- Advisory Groups
- Conflicts of Interest
- Dispute Resolution Process
- Governing Council
- QHIN Security of TEFCA Information
- QHIN Cybersecurity Insurance
- Transitional Council

Additional SOPs will be made available over time.

What is a Standard Operating Procedure? An SOP is a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into this Common Agreement to provide detailed information or requirements related to the exchange activities under the Common Agreement, including all amendments thereto and any new SOPs that are adopted pursuant to the Common Agreement. SOPs will be adopted to address the application process, the Onboarding process, and other operational processes. Each SOP identifies the relevant group(s) to which the SOP applies, including whether Participants and/or Subparticipants are required to comply with a given SOP. An SOP shall be deemed in effect when adopted pursuant to Section 5.3 of this Common Agreement and listed on a public website.

What is the QHIN Technical Framework?



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The QHIN Technical Framework (QTF) outlines the technical specifications and other technical requirements necessary for QHINs to accomplish exchange.

The QTF primarily addresses QHIN-to-QHIN transactions, and is generally silent on how the necessary functional outcomes are achieved within a QHIN.

There are some requirements that must be enforced at the Participant and Subparticipant level.

The QTF is available at RCE.SequoiaProject.org





Query

- Patient Query
- Document Query
- Document Retrieve



Message Delivery

Note: Entities within a QHIN's network must respond to queries for Exchange Purposes in accordance with the Common Agreement and applicable law, but do not have to be able to receive data sent to them using message delivery.

Three-Year FHIR Roadmap for TEFCA



- ONC and the RCE have published the [“FHIR® Roadmap for TEFCA Exchange – Version 1.”](#)
- Evolving health IT landscape requires TEFCA to rapidly include approaches that support FHIR.
 - » Approach leverages current state of FHIR today and allows TEFCA policy and technical infrastructure to accelerate FHIR adoption into the future.
 - » In 2022, the RCE will launch working groups to initiate development of the use of FHIR for both QHIN-brokered and facilitated FHIR exchange.

Planned Stages of FHIR Availability in TEFCA:

Stage 1: FHIR Content Support

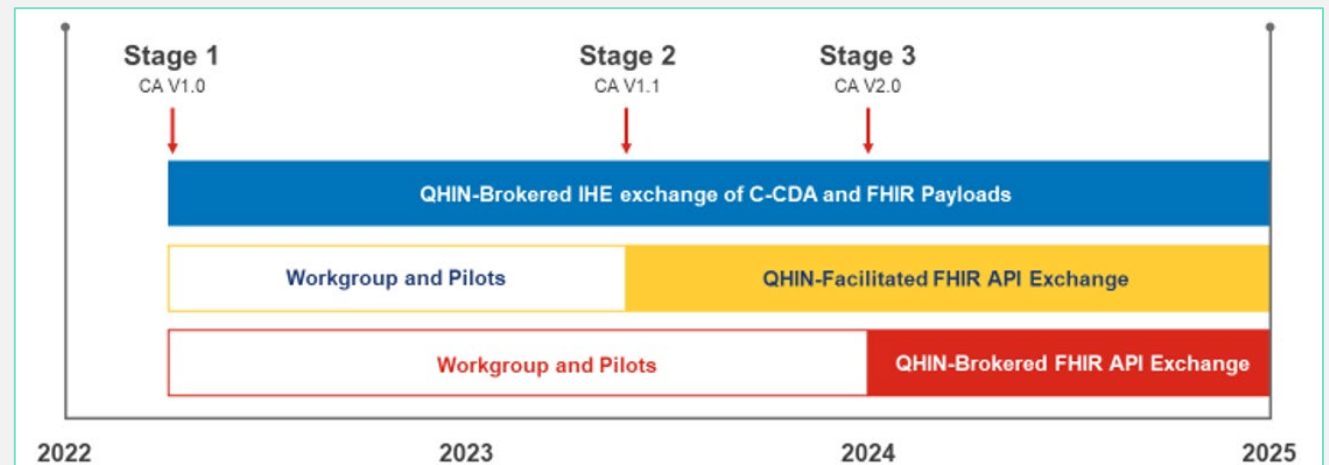
- FHIR exchange possible within QHINs’ own networks
- IHE exchange of FHIR payloads between QHINs *is possible with “out-of-band” coordination.*

Stage 2: Network-Facilitated FHIR Exchange

- QHIN-facilitated FHIR-based exchange available as an *option* under TEFCA.

Stage 3: Network-Brokered FHIR Exchange

- QHIN-facilitated FHIR-based exchange *required* under TEFCA
- QHIN-brokered FHIR API exchange *optionally* available.



QHIN Eligibility Criteria, Onboarding, and Designation

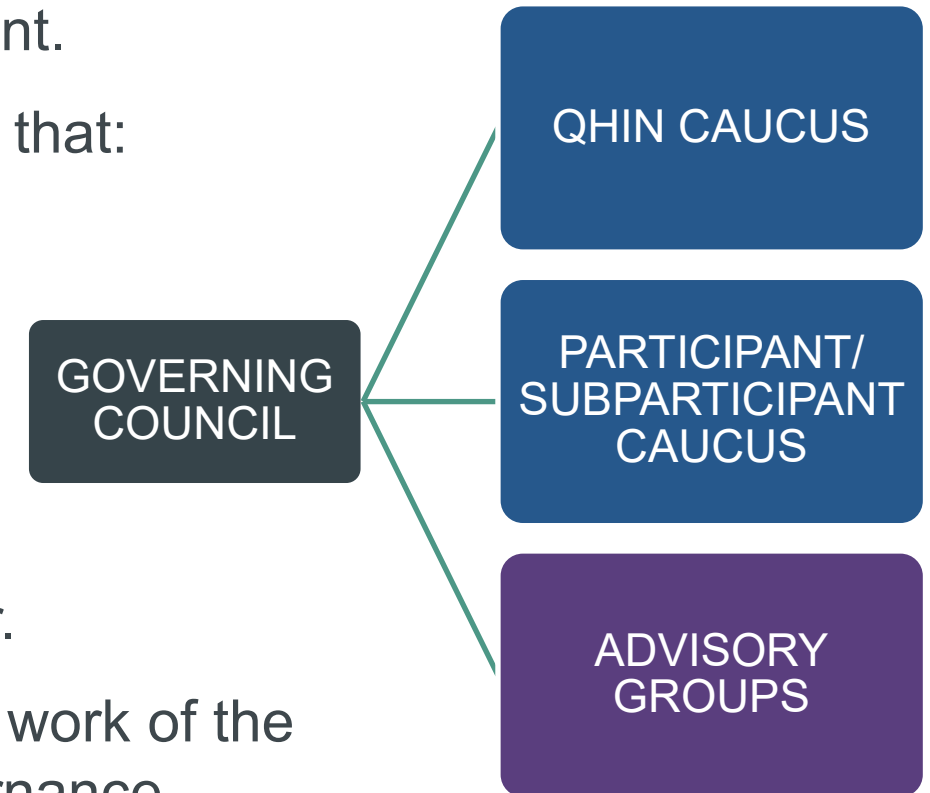


- TEFCA includes QHIN eligibility criteria that generally address:
 - » The ability to perform the required functions of a QHIN, per the QTF.
 - » The legal structure and governing approach for a QHIN.
 - » Demonstrated resources and infrastructure to support a reliable and trusted network.
- QHINs will be expected to provide ongoing reporting on metrics and other information needed to monitor performance over time.
- The RCE will conduct extensive education for candidate QHINs on the application and onboarding processes.
- Only the RCE designates QHINs.





- QHINs, Participants, and Subparticipants shall have the opportunity to engage in governance under the Common Agreement.
- The Common Agreement creates a Governing Council that:
 - » Reviews amendments to the Common Agreement, QTF, and SOPs.
 - » Serves as a resource to the RCE and forum for discussion.
 - » Provides oversight for resolution of disputes.
- A Transitional Council serves during TEFCA's first year.
- Under the Cooperative Agreement, ONC oversees the work of the RCE, which has specific obligations to follow the governance procedures set forth in the Common Agreement.





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What are the Exchange Purposes under TEFCA and how do they work?

- The Exchange Purpose identifies the reason for which information could be requested or shared through QHIN-to-QHIN exchange.
- Only these six Exchange Purposes are authorized under the Common Agreement.
- A forthcoming SOP will specify that Treatment and Individual Access Services (IAS) require Responses.
- Eventually, the other four Exchange Purposes will require Responses in conformance with forthcoming implementation guides. These will be rolled out with adequate time for stakeholders to prepare.
- Additional Exchange Purposes may be added over time, including whether they require Responses.

Permitted Exchange Purposes



Treatment



Payment



Health Care Operations



Public Health

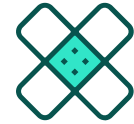


Government Benefits Determination



Individual Access Services

- “**Treatment,**” “**Payment,**” and “**Health Care Operations**” generally have the same meaning as they have under the HIPAA Privacy Rule and apply to all TEFCA Information, regardless of whether the parties to exchange are HIPAA Covered Entities or Business Associates.
- The **Public Health** Exchange Purpose includes Requests for Uses and Disclosures of information by Public Health Authorities that are consistent with the HIPAA Privacy Rule and other Applicable Law.
- The **Government Benefits Determination** Exchange Purpose supports governmental agencies that need information to determine whether a person qualifies for non-health government benefits in a manner that is consistent with the HIPAA Privacy Rule and other Applicable Law.
- The Common Agreement anticipates the use of consumer-facing applications that would assist Individuals in obtaining access to their health information. This Exchange Purpose is called **Individual Access Services**.



Individual Access Services (IAS)



What is IAS?

IAS is, with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.

In general, entities are required to Respond to Requests for information for the purpose of Individual Access Services.

What is an IAS Provider?

Each QHIN, Participant, and Subparticipant that offers Individual Access Services.

It is optional to be an IAS Provider.

Individuals will be able to access their own information from all connected entities through an IAS Provider.





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What privacy and security requirements are included in TEFCA?



TEFCA will provide strong privacy protections.

- Most connected entities will likely be HIPAA Covered Entities or Business Associates of Covered Entities, and thus already be required to comply with HIPAA privacy and security requirements.
 - » As a matter of general policy, once TEFCA Information (TI) is received by a QHIN, Participant, or Subparticipant that is a Covered Entity or Business Associate and is incorporated into such recipient's system of records, the information is no longer TI and is governed by the HIPAA Rules and other Applicable Law.
- The Common Agreement requires each Non-HIPAA Entity to protect individually identifiable information that it reasonably believes is TEFCA Information in substantially the same manner as HIPAA Covered Entities protect Protected Health Information (PHI), including most provisions of the HIPAA Privacy Rule.
 - » This includes, for example, Health Care Providers and IAS Providers that are non-HIPAA Entities.
 - » IAS Providers have additional requirements (see later slides).





TEFCA will provide strong security protections.

- QHINs will be expected to meet a high bar for security, including:
 - » Third-party certification to industry-recognized cybersecurity standards, in addition to complying with the HIPAA Security Rule.
 - » Annual security assessments.
 - » Have a Chief Information Security Officer.
 - » Have cyber risk coverage.
- Flow-down contract provisions for all Participants and Subparticipants:
 - » Non-HIPAA Entities (NHEs) must comply with the HIPAA Security Rule with respect to all individually identifiable information that the entity reasonably believes is TEFCA Information.
- Notice of TEFCA Security Incidents involving or affecting exchange:
 - Are required of QHINs, Participants and Subparticipants.
 - Generally designed to avoid conflict with Applicable Law and duplicative notification requirements.
- All TEFCA entities shall evaluate the risks of any Uses and/or Disclosures of TEFCA Information outside the U.S to evaluate whether they satisfy the HIPAA Security Rule.
- The RCE will actively facilitate security activities, with the support of a Cybersecurity Council drawn from participating QHINs.





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How do you become a QHIN?



The RCE will support prospective QHINs:

- Educational opportunities
- Eligibility criteria in the Common Agreement
- Application
- QHIN Onboarding & Designation SOP
- Designated Point of Contact



For more information on the QHIN application process, visit: www.RCE.SequoiaProject.org.

QHIN Application Process

Pre-application Activities



Prospective QHIN reviews the Common Agreement, QTF, and SOPs.

Prospective QHIN participates in educational sessions.



Prospective QHIN signs the Common Agreement and submits QHIN Application package.

The RCE makes an eligibility determination.

QHIN onboarding



If application is accepted, prospective QHIN begins the QHIN onboarding process, including technical testing and production connectivity validation.



If all requirements are met, RCE counter-signs the Common Agreement and designates the applicant as a QHIN.



RCE provides written notice of QHIN Designation to both the applicant and ONC.

All relevant materials and resources will be available at www.RCE.SequoiaProject.org.



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How will TEFCA be operationalized?

Timeline to Operationalize TEFCA

2021

- Public engagement
- Common Agreement Work Group sessions
- RCE and ONC use feedback to finalize TEFCA

Q2 of 2022

- QHINs begin signing Common Agreement and applying for designation

2023

- Establish Governing Council
- Follow change management process to iterate Common Agreement, SOPs, and QTF, including to support FHIR-based exchange



Q1 of 2022

- Publish Common Agreement Version 1
- Publish QHIN Technical Framework (QTF) Version 1 and FHIR Roadmap
- Initiate work to enable FHIR-based exchange
- Public education and engagement

Q3 and Q4 of 2022

- Onboarding of initial QHINs
- Additional QHIN applications processed
- RCE establishes Transitional Council
- RCE begins designating QHINs to share data
- Prepare for TEFCA FHIR exchange pilots



Resources

- Common Agreement v. 1
- QHIN Technical Framework
- FHIR® Roadmap for TEFCA
- Standard Operating Procedures
- User's Guide
- Benefits of TEFCA by Stakeholder Factsheets
- FAQs

<https://rce.sequoiaproject.org/tefca-and-rce-resources/>

Additional Resources:

<https://www.healthit.gov/tefca>

Events

- 1/26: Common Agreement Overview Webinar
- 2/2: QHIN Technical Framework (QTF) & FHIR® Roadmap Webinar
- 2/3: Common Agreement & Standard Operating Procedures (SOPs) Webinar
- 3/8: TEFCA Panel at ViVE
- 3/14: Morning Keynote at HIMSS Pre-Conference Symposium
- 3/15: TEFCA Education Session at HIMSS

<https://rce.sequoiaproject.org/community-engagement/>



Questions & Answers



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Visit www.RCE.SequoiaProject.org to
view the Common Agreement Version 1.