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February 3, 2022

Overview of the Common Agreement and Standard Operating Procedures

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



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This program is supported by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) under grant number 90AX0026, Trusted Exchange Framework and Common Agreement - Recognized Coordinating Entity (RCE) Cooperative Agreement Program, in the amount of \$2,919,000 with 100 percent funded by ONC/HHS. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by ONC, HHS or the U.S. Government.



- How will exchange work under TEFCA?
- What are the components of TEFCA?
- What are the Exchange Purposes under TEFCA?
- What is in the Common Agreement Version 1?
- What Standard Operating Procedures have been released?
- How will TEFCA be operationalized?
- Questions & Answers

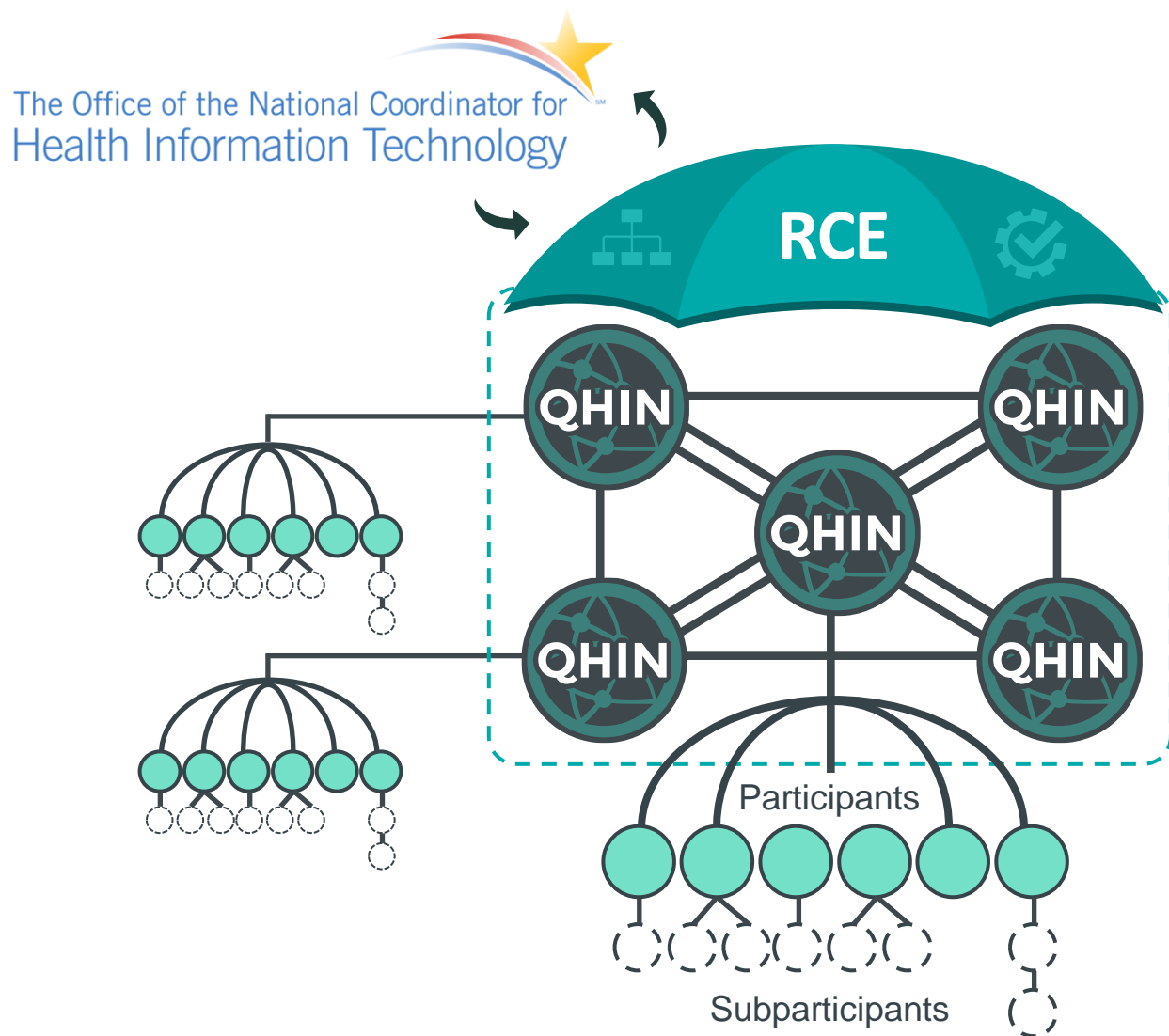


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How will exchange work under TEFCA?

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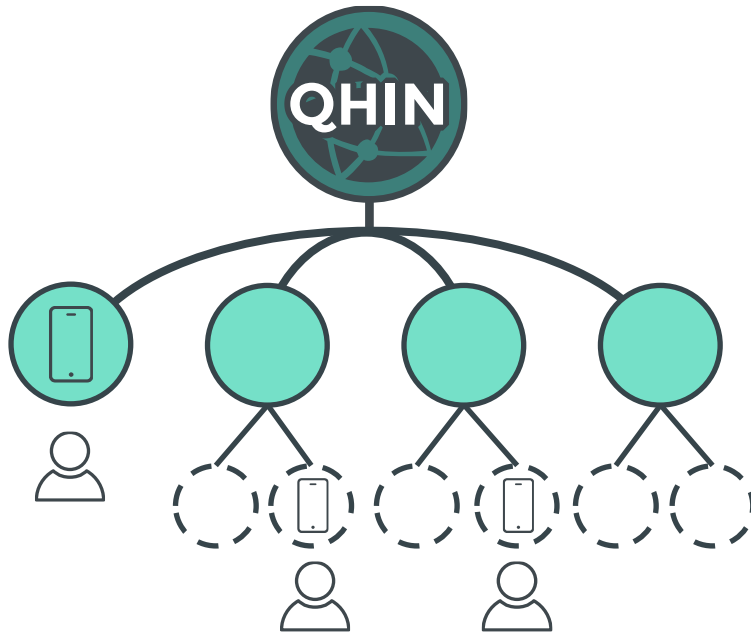






- ← ONC defines overall policy and certain governance requirements.
- ← RCE provides oversight and governing approach for QHINs.
- ← Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.
- ← Each QHIN connects Participants, which connect Subparticipants.

The Role of a Qualified Health Information Network



QHIN Example



-  Participant
-  Subparticipant
-  Consumer App offered by Participant or Subparticipant
-  Individual

A **QHIN** is an entity with the technical capabilities and organizational attributes to connect health information networks on a nationwide scale.

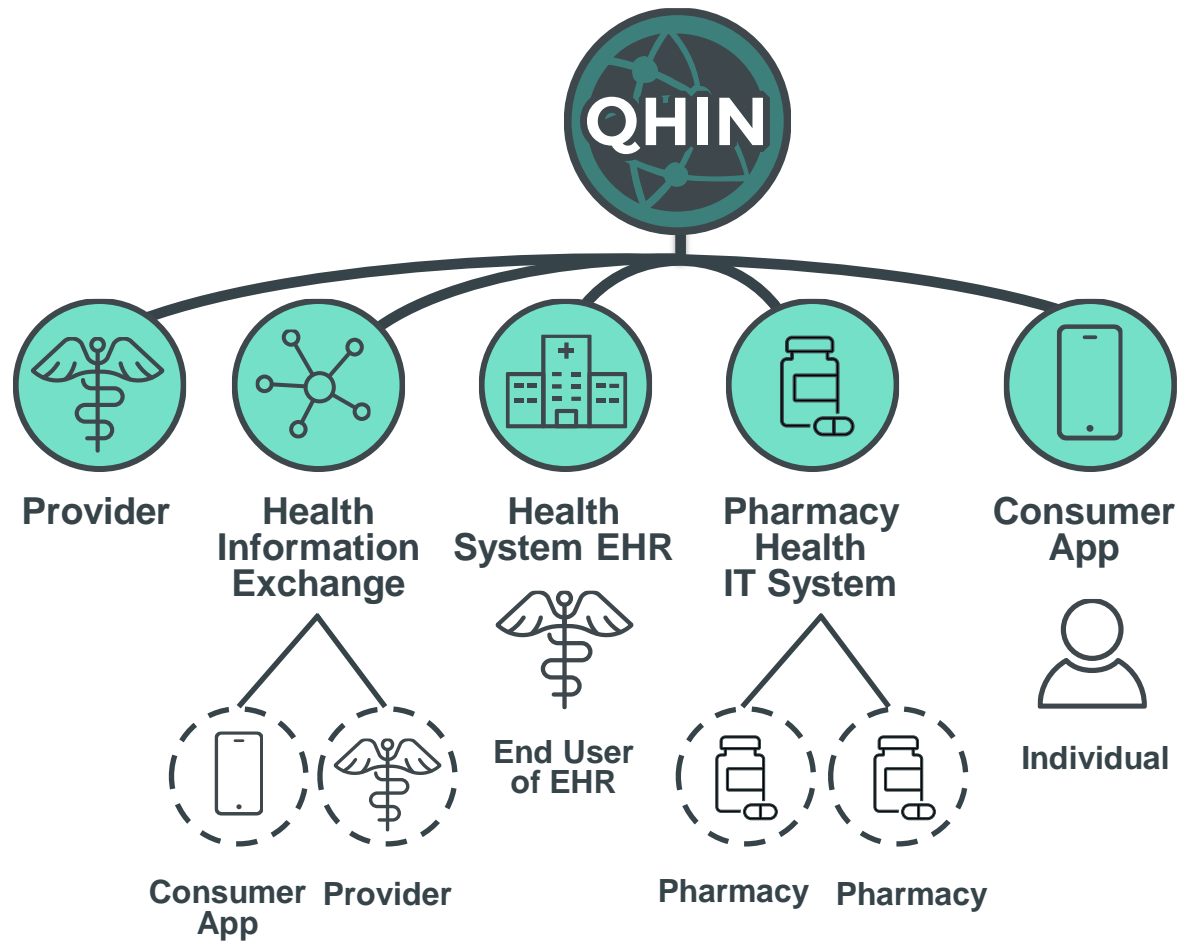
- High volume
- High reliability
- Abides by the Common Agreement
- Adheres to the QHIN Technical Framework

Participants and Subparticipants will be able to choose their QHIN based on the services provided and fees charged.

Participants and Subparticipants will be able to share information with all other connected entities regardless of which QHIN they choose.

QHINs may not charge fees to other QHINs for any exchange of information under the Common Agreement.

Example of QHIN, Participants, and Subparticipants



In this example, the QHIN supports a broad range of different Participants, including a provider, a health information exchange (HIE), an Electronic Health Record (EHR) system, a pharmacy health information technology (IT) system, and a consumer application that is an Individual Access Services (IAS) Provider.

The members of the HIE and the pharmacy health IT system are Subparticipants.

Individuals can connect to QHINs, Participants, and Subparticipants that choose to be IAS Providers. In this example, one consumer app is a Participant of the QHIN and another consumer app is a Subparticipant of the HIE.



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What are the components of TEFCA?

TEFCA Components



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**Focus of
today's
Webinar**

**Focus of
today's
Webinar**



Trusted
Exchange
Framework



Common
Agreement



Standard
Operating
Procedures



QHIN
Technical
Framework



QHIN
Onboarding



Metrics



Governing
Approach



- 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).





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.

Framework Agreement Flow-Down Provisions



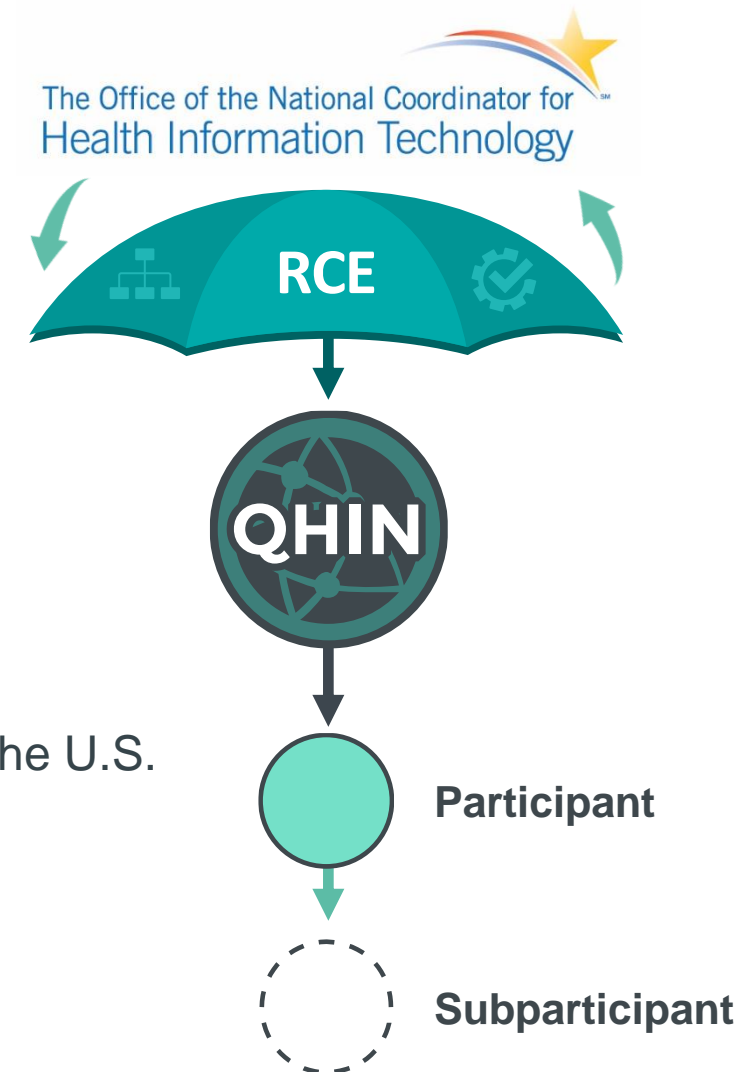
Common Agreement

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.”





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What are the Exchange Purposes under TEFCA?

- 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

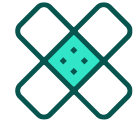


Government Benefits Determination



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**.





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What is in the Common Agreement Version 1?

Sections of the Common Agreement



1. Definitions and Relevant Terminology
2. Incorporation of Recitals
3. Governing Approach
4. QHIN Designation
5. Change Management
6. Cooperation and Non-Discrimination
7. Confidentiality and Accountability
8. RCE Directory
9. TEFCA Exchange Activities
10. Individual Access Services
11. Privacy
12. Security
13. General Obligations
14. Specific QHIN Obligations
15. Dispute Resolution
16. Stability of the QHIN Network
17. Fees
18. Contract Administration



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QHIN Eligibility Criteria, Onboarding, and Designation

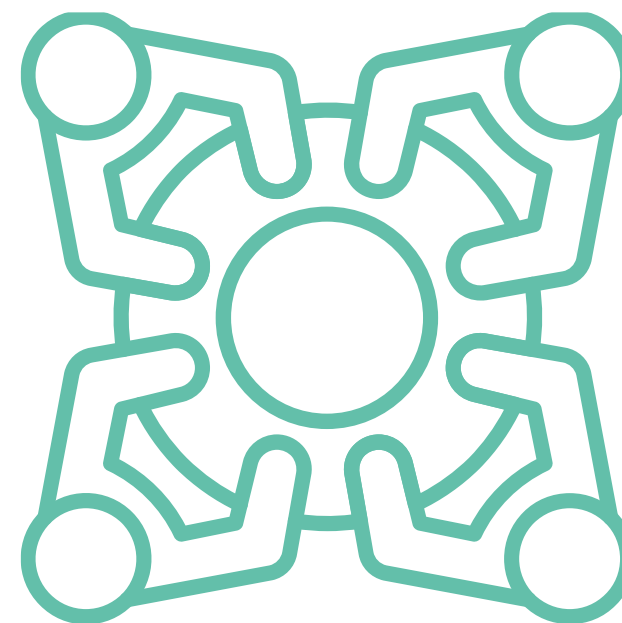


- TEFCA includes QHIN eligibility criteria that generally address:
 - » The ability to perform the required functions of a QHIN, per the QTF.
 - » The legal structure and governing approach for a QHIN.
 - » Demonstrated resources and infrastructure to support a reliable and trusted network.
- QHINs will 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.





- The Common Agreement specifies expectations of QHINs, Participants, and Subparticipants to ensure that all parties cooperate in certain aspects of exchange such as:
 - » Timely responses to inquiries.
 - » Notification of persistent and widespread connectivity failures.
 - » Support in resolving issues.
 - » Sharing information regarding cybersecurity risks.
- QHINs, Participants, and Subparticipants are prohibited from limiting interoperability with others in a discriminatory manner.





- **TEFCA Requests** will be transmitted via a QHIN-to-QHIN exchange and consistent with the requirements of the Common Agreement.
 - » Only QHINs and certain Participants or Subparticipants can make Requests for each Exchange Purpose.
- **Uses and Disclosures** must adhere to the privacy and security requirements in the Common Agreement, any privacy and security notices, and any requirements of applicable law.



As will be specified in a forthcoming SOP, Requests for Treatment and Individual Access Services are the first types of Exchange Purposes to which TEFCA entities are required to Respond.

Responses would not be required if providing the information is prohibited by Applicable Law or the Common Agreement permits but does not require a Response (see the Common Agreement Section 9.4.1, Exceptions to Required Responses).



The following entities are permitted, but not required, to Respond to Requests:

- Public Health Authorities.
- Users of Government Benefits Determination Exchange Purpose.
- Federal agencies, to the extent that the requested Disclosure of Required Information is not permitted under Applicable Law.



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What Standard Operating
Procedures have been
released?

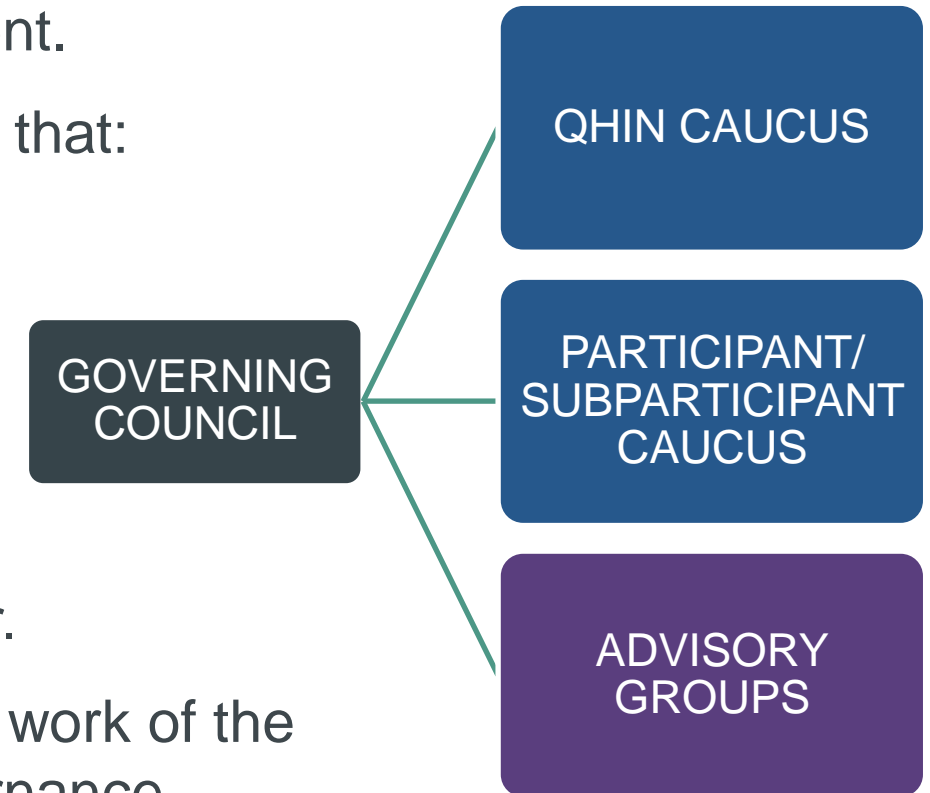
SOPs Related to the TEFCA Governing Approach



Standard Operating Procedure	Purpose
TEFCA Governing Council	This SOP provides the specifics for the composition, conduct and other issues for the Governing Council.
Transitional Council	The RCE recognizes that it will take some period of time to Designate QHINs. The RCE's working assumption is that some organizations will seek to be Designated as QHINs shortly after the Common Agreement is published and that other organizations will pursue Designation over the first year or two after the Common Agreement is published. The RCE believes that the first QHINs will want a role in governance and this Transitional Council will serve this role. This SOP provides the specifics for the composition.
Advisory Groups	This SOP sets out the way in which Advisory Groups will be established and the general rules that govern the activity of an Advisory Group. The RCE and the Governing Council may choose to use Advisory Groups in a variety of ways including, but not limited to, the following: giving feedback on possible changes to the Common Agreement, the QTF, or an SOP; or, providing feedback on new Exchange Purposes. These are meant as examples only and should not be considered to limit the manner in which the RCE may choose to use Advisory Groups.



- 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.





- **Purpose:** It is important that the RCE have a process to assure that each individual who serves will act in the best interests of the activities under the Common Agreement in all their decisions. This will help promote trust in the decisions that are made by any Deliberative Body.
- **Procedure:**
 1. Disclosure of Actual and Potential Conflicts of Interest
 2. Recusal from any discussion of a matter that involves an Actual Conflict of Interest
 3. Case-by-case consideration of Potential Conflict of Interest
 4. Appeal process





- **Purpose:** The Common Agreement provides a mechanism for Disputes to be resolved via a collaborative process so that QHINs and the Governing Council are not required to seek resolution of their Disputes via litigation. This SOP describes the process that QHINs will use in the Dispute Resolution Process.
- **Procedure:**
 1. Informal Conference
 2. Dispute Resolution Council
 3. Disputes between QHINs and/or Their Participants
 4. Appeal to the Governing Council



SOP – QHIN Security Requirements for the Protection of TEFCA Information



- **Purpose:** This SOP identifies specific requirements that QHINs must follow to protect the security of TI. It also provides specific information about the Cybersecurity Council.
- **Procedure:**
 1. Third-Party Cybersecurity Certification
 2. Annual Technical Audits
 3. Security Documentation Requirements
 4. Confidentiality of Security Documentation
 5. Cybersecurity Council

The Cybersecurity & Infrastructure Security Agency (CISA) has identified the healthcare and public health sector as part of the nation's critical infrastructure, stating: The Healthcare and Public Health Sector protects all sectors of the economy from hazards such as terrorism, infectious disease outbreaks, and natural disasters. Because the vast majority of the sector's assets are privately owned and operated, collaboration and information sharing between the public and private sectors is essential to increasing resilience of the nation's Healthcare and Public Health critical infrastructure



- **Purpose:** The purpose of this SOP is to ensure that each QHIN has cyber risk and technology errors and omissions insurance and/or internal financial reserves in amounts not less than the liability limits presently stated in Section A of this SOP then in effect.
- **Procedure A:** In Relation to Liability Limits
 1. For purposes of this Cybersecurity Coverage SOP, a QHIN must have demonstrated the ability to fulfill its obligation to cover any liability up to the liability limits...
 2. A QHIN may demonstrate its ability to fulfill its obligations through a combination of measures including a policy or policies of insurance for cyber risk and technology errors and omissions and/or internal financial reserves.

Section 7.4 of the Common Agreement states, in relevant part: “IN NO EVENT SHALL EITHER RCE’S OR SIGNATORY’S TOTAL LIABILITY TO EACH OTHER AND ALL OTHER QHINS ARISING FROM OR RELATING TO THIS AGREEMENT EXCEED AMOUNTS EQUAL TO TWO MILLION DOLLARS (\$2,000,000) PER INCIDENT AND FIVE MILLION DOLLARS (\$5,000,000) AGGREGATE PER ANNUM OR SUCH OTHER AMOUNTS AS STATED IN A THEN-IN-EFFECT SOP....”



- **Procedure B: Cybersecurity Coverage**
 1. Cybersecurity Coverage Requirements
 - (a) A policy of insurance for cyber risk/technology errors and omissions with coverage in amounts not less than the Liability Limit;
 - (b) Internal financial reserves to “self-insure” against a cyber-incident in amounts not less than the Liability Limit; or
 - (c) Some combination of cyber risk/technology errors and omissions insurance and internal reserves in amounts not less than the Liability Limit.
 2. Evidence of Cybersecurity Coverage
 3. Notification of Changes
 4. Attestation of Compliance
 5. Effect of Insurance and/or Reserves





- TEFCA will function within the constraints of Applicable Law, including state, local, tribal, and federal law.
- If there is a conflict between Applicable Law and provisions of the Common Agreement, the order of precedence is as follows:
 - i. Applicable Law;
 - ii. The Common Agreement including the Required Flow-Down provisions to be included in the agreements between TEFCA Entities;
 - iii. The QHIN Technical Framework (QTF);
 - iv. The Dispute Resolution Process, as set forth in the Common Agreement and an SOP;
 - v. All other SOPs; and
 - vi. All other attachments, exhibits, and artifacts incorporated into the Common Agreement by reference; and
 - vii. Other RCE plans, documents, or materials made available regarding activities conducted under the Framework Agreements.
- An entity **Disclosing** data must follow the Applicable Law that applies to it for disclosing data.
- An entity **Requesting** data must follow the Applicable Law that applies to it for the actions it takes in making Requests.



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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

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.



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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