July 16, 2024

RCE™ Monthly Information Call

Zoe Barber, RCE Policy Director
Johnathan Coleman, RCE CISO
Didi Davis, RCE Conformance Testing
Dawn Van Dyke, RCE Communications Lead
Lindsey Elkind, RCE Legal SME
Kathryn Lucia, RCE Policy Analyst
Dave Pyke, RCE Technical SME
Steve "Sully" Sullivan, RCE Program Operations
Alan Swenson, RCE Program Operations Lead
Erin Whaley, RCE Legal SME
Chantal Worzala, RCE Stakeholder Engagement
Mariann Yeager, RCE Lead

Agenda

- **ONC Welcome**
- **TEFCA^{TM} Exchange Basics**
- **TEFCA Timeline Review**
- **New and Updated Standard Operating Procedures (SOPs)**
  - Exchange Purposes (XPs) SOP Version 2.0
  - Treatment Exchange Purpose (XP) Implementation SOP Version 1.0
  - Delegation of Authority SOP Version 1.0
  - RCE Directory Service Requirements Policy SOP Version 1.0
  - Individual Access Service (IAS) Provider Requirements SOP Version 2.0
  - Governance Approach SOP Version 1.0
  - Expectations for Cooperation SOP Version 1.0
  - TEFCA Security Incident Reporting SOP Version 1.0
- **Technical Document Updates**
  - QHIN Technical Framework (QTF) Version 2.0
  - Facilitated Fast Healthcare Interoperability Resources (FHIR) Implementation SOP Version 1.0
- **Educational Resources and FAQs**
- **Questions & Answers (Q&A)**

HL7® FHIR®

TEFCA is Live and Looking to the Future with FHIR!

ONC Welcome

Steve Posnack
Deputy National Coordinator for Health Information Technology

TEFCA Exchange Basics

TEFCA is Live!

commonwell HEALTH ALLIANCE

eHealth Exchange™

Epic Nexus

HEALTH GORILLA

Kno2

KONZA NATIONAL NETWORK

MedAllies

https://rce.sequoiaproject.org/designated-qhins/

Letters of Intent
- Inactive – 10
- Active – 2

Completeness Review
- 0

Applications Accepted
- 1

Partner Testing & Project Plan Completion
- 0

Submitting Application
- 0

Definitive Review
- 0

Conformance Testing
- 2

Designated
- 7
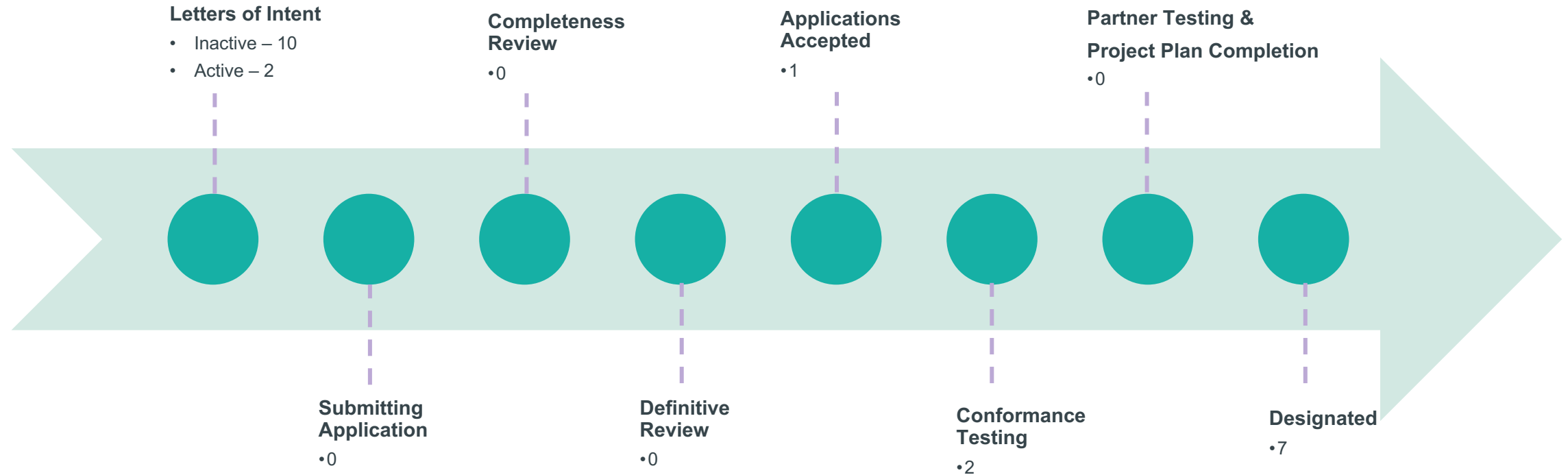
TEFCA Components

Framework Agreements

Standard Operating Procedures

Technical Requirements

RCE Directory

Oversight & Compliance
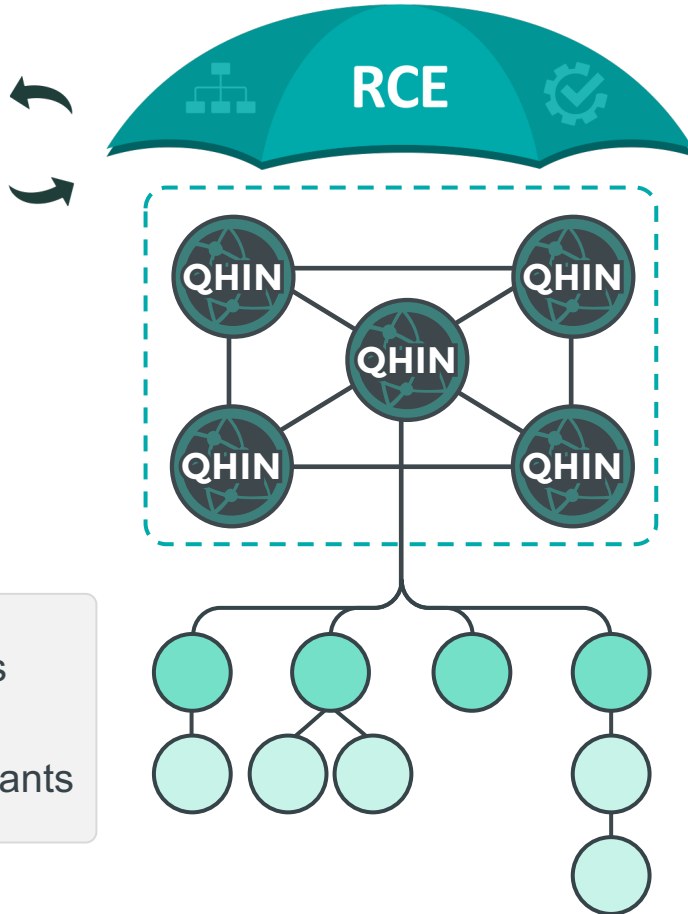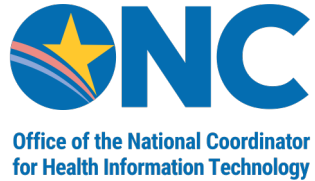
Governance

Exchange Under TEFCA

Participants

Subparticipants

ONC defines overall policy and certain governance requirements

RCE provides oversight and governing approach for QHINs

QHINs connect directly to each other to facilitate nationwide interoperability

Each QHIN connects Participants, which connect Subparticipants

Participants and Subparticipants connect to each other through TEFCA Exchange

- Participants contract directly with a QHIN and may choose to also provide connectivity to others (Subparticipants), creating an expanded network of networks

- Participants and Subparticipants sign the same Terms of Participation and can generally participate in TEFCA Exchange in the same manner

Framework Agreements and TEFCA connections

Common Agreement
Each QHIN voluntarily enters into the same contractual agreement with the RCE by signing the Common Agreement

Participant/Subparticipant Terms of Participation
All Participants and Subparticipants voluntarily agree to the Terms of Participation without modification as part of their agreements with their TEFCA connector
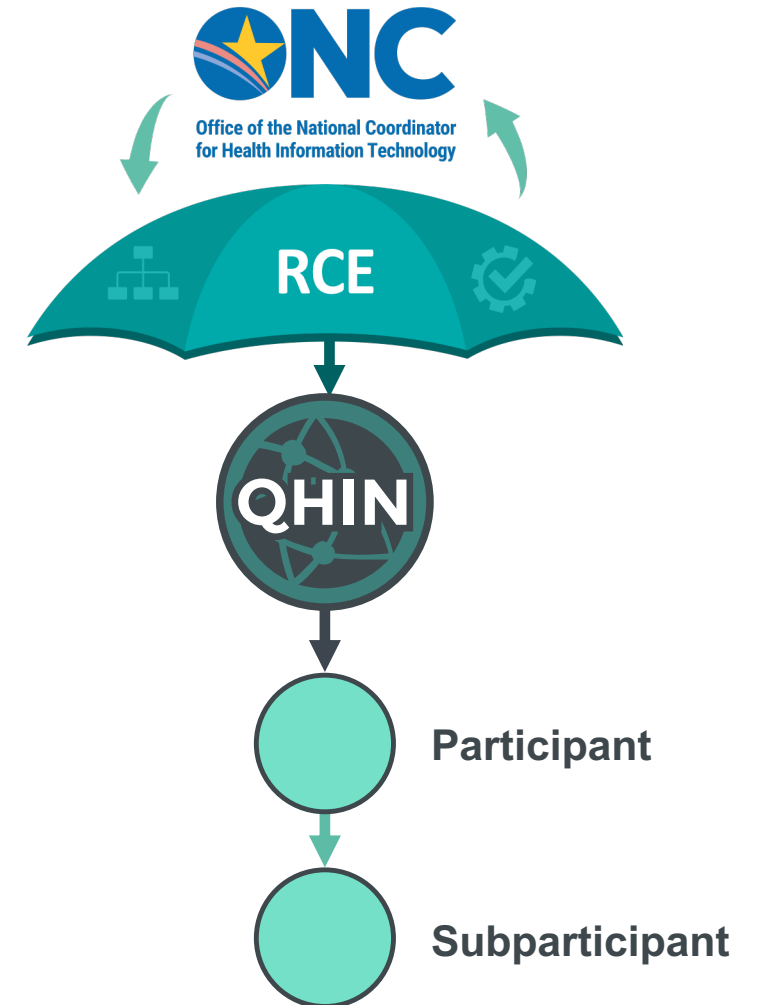
TEFCA connector
A QHIN, Participant, or Subparticipant that offers services to connect into TEFCA exchange

TEFCA connected entity
A QHIN, Participant, or Subparticipant that has signed a Framework Agreement

Entities may connect into exchange at any level

Standard Operating Procedures (SOP)

What is an SOP?

- An SOP is a written procedure or other provision that is incorporated by reference into the Framework Agreements to provide detailed information or requirements related to TEFCA Exchange

- SOPs address, among other things, governance, privacy and security requirements, RCE directory services, and QHIN application and designation

- Each SOP identifies the parties to which it applies (QHINs, Participants, Subparticipants)

What is the Exchange Purposes (XPs) SOP?

The XPs SOP details specifications relevant to when and how information can be requested or shared through TEFCA Exchange

What is an Exchange Purpose (XP) Implementation SOP?

XP Implementation SOPs provide additional details for specific use cases, as needed

Why SOPs?

- SOPs create the flexibility for TEFCA to evolve and expand over time

- SOPs will be created and modified as needed and finalized through a defined change management process

- Access the SOPs on the RCE website

Authorized Exchange Purposes (XPs) and XP Codes

Authorized XP	XP Code	Level
Treatment	T-TREAT	Level 1
TEFCA Required Treatment	T-TRTMNT	Level 2
Payment	T-PYMNT	Level 1
Health Care Operations	T-HCO	Level 1
Public Health	T-PH	Level 1
Electronic Case Reporting	T-PH-ECR	Level 2
Electronic Lab Reporting	T-PH-ELR	Level 2
Individual Access Services	T-IAS	Level 1
Government Benefits Determination	T-GOVDTRM	Level 1

A Level 1 XP Code identifies an authorized Exchange Purpose (XP)

A Level 2 XP Code identifies a specific use case within an authorized XP and may reference specific technical requirements

TEFCA Timeline Review

Common Agreement Versions At-a-Glance

January 2022

Common Agreement — V 1

The Common Agreement version 1 was the initial version of the Common Agreement and reflected policies developed with extensive public input.

Related QTF Version: 1
Related FHIR Roadmap Version: 1

December 2023

Common Agreement — V 1.1

The Common Agreement version 1.1 included changes required by HHS prior to TEFCA exchange going live. *This is the version in operation as of the official launch of TEFCA exchange.*

Related QTF Version: 1.1
Related FHIR Roadmap Version: 2

July 2024

Common Agreement — V 2.0

The Common Agreement version 2.0 includes enhancements and updates to require support of HL7 FHIR® based transactions.

Related QTF Version: 2 – DRAFT
Related FHIR Roadmap Version: 2

Transition from Version 1.1 to Version 2.0

- **TEFCA is currently live on Common Agreement Version 2.0 for QHINs**
- Applicable Flow-Down provisions are applied to Participants and Subparticipants
- There is a transition period to allow for adoption of the new Framework Agreements by those who are already live
  - o 60 days for the Common Agreement
  - o 180 days for the Terms of Participation
- During the transition, all TEFCA connected entities can engage in TEFCA Exchange for approved Exchange Purposes
- QHINs are responsible for adding new TEFCA connected entities to the RCE Directory as they sign the Terms of Participation

May 2024	June/July 2024	Summer 2024	December 2024
• May 1: Common Agreement and Terms of Participation published in Federal Register	• July 1: Common Agreement 2.0 is effective for QHINs (60 days after publication) • RCE and newly designated QHINs sign version 2.0 • Final QTF version 2.0 published and expected to be in production • Facilitated FHIR SOP expected to be published and in production • New Participants and Subparticipants sign the Terms of Participation	• Additional SOPs are released on a rolling basis	• Dec 27: Terms of Participation compliance date for any Participant / Subparticipant that signed a flow down agreement prior to June 30th

https://www.federalregister.gov/documents/2024/05/01/2024-09476/notice-of-publication-of-common-agreement-for-nationwide-health-information-interoperability-common).

Expected SOP Batch Release

Published July 1, 2024

- QHIN Technical Framework (QTF) Version 2.0
- Facilitated FHIR Implementation SOP
- Individual Access Services (IAS) Provider Requirements
- Governance Approach SOP
- Delegation of Authority SOP
- Expectations for Cooperation SOP
- Exchange Purposes SOP
- RCE Directory Service Requirements Policy SOP
- Security Incident Reporting SOP
- XP Implementation SOP: Treatment

Expected Summer/Fall 2024

- XP Implementation SOP: IAS Demographic Matched
- XP Implementation SOP: Public Health
- XP Implementation SOP: Health Care Operations
- QHIN Security for the Protection of TEFCA Information (TI)
- Participant/Subparticipant Additional Security Requirements SOP
- QHIN Onboarding & Designation/Application SOP
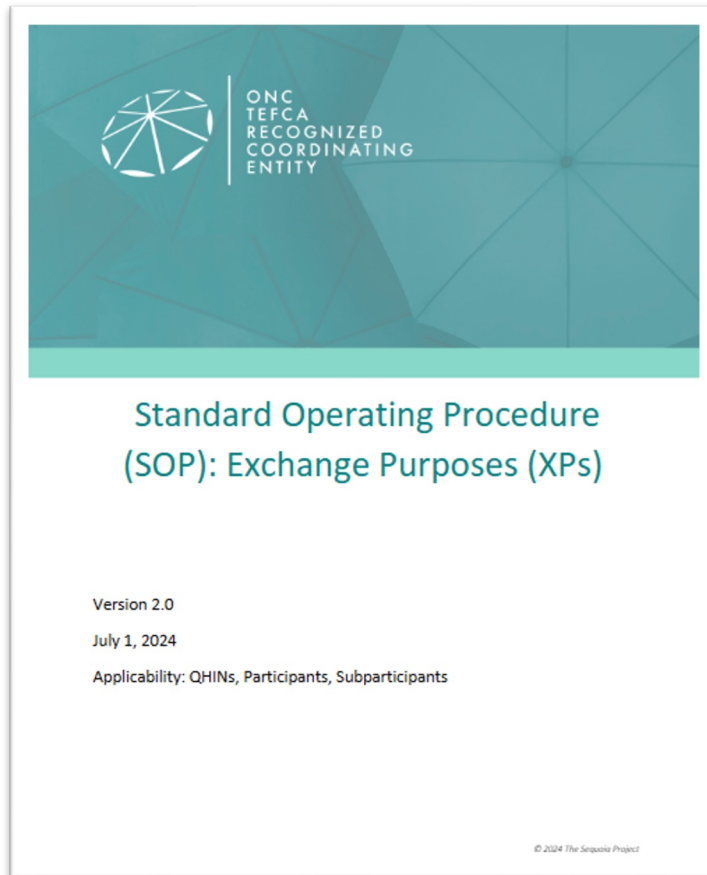- QHIN Application SOP
- Updated Governance SOP

July 1
New & Updated SOPs

The information contained in these slides is abbreviated from the Standard Operating Procedures (SOPs). For comprehensive details and specific requirements, please refer to the complete SOP documentation.

Standard Operating Procedure (SOP): Exchange Purposes (XPs)

Version 2.0

July 1, 2024

Applicability: QHINs, Participants, Subparticipants

© 2024 The Sequoia Project

Purpose: This SOP defines the authorized XPs and identifies any XPs for which a Response is required pursuant to the Common Agreement, as well as when fees are prohibited or permitted. More information on implementation of each XP may be found in an XP Implementation SOP, as applicable.

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   • 4.1 Authorized Exchange Purposes (XPs) and XP Codes
   • 4.2 Required Information and Permitted Fees
   • 4.3 Limitations on Types of Participants/Subparticipants
   • 4.4 Required Support
   • 4.5 Required Responses
   • 4.6 Exceptions to Required Responses

SOP: Exchange Purposes (XPs)

TABLE 2. REQUIRED RESPONSE AND PERMITTED FEES

Authorized XP	XP Code	Required Response (Yes/No)	Permitted Fees (Yes/No)
Treatment	T-TREAT	No	No
TEFCA Required Treatment	T-TRTMNT	Yes	No
Payment	T-PYMNT	No	Yes
Health Care Operations	T-HCO	No	Yes
Public Health	T-PH	No	Yes
Electronic Case Reporting	T-PH-ECR	No	Yes
Electronic Lab Reporting	T-PH-ELR	No	Yes
Individual Access Services	T-IAS	Yes	No
Government Benefits Determination	T-GOVDTRM	No	Yes

Key Highlights

- Each transaction must be accompanied by the appropriate XP Code

- Table 2 list the XPs that require Response, unless an exception applies, per the XPs SOP

- Responses to required XPs must include all Required Information maintained

- Responding Nodes may only charge fees to an Initiating Node if permitted in table 2

- The XPs SOP lists the exceptions to required Responses

Standard Operating Procedure (SOP): Exchange Purpose (XP) Implementation: Treatment

Version 1.0

July 1, 2024

Applicability: QHINs, Participants, Subparticipants

© 2024 The Sequoia Project

Purpose: In addition to the Common Agreement, QTF, and applicable SOPs, this SOP identifies implementation specifications QHINs, Participants, and Subparticipants must follow when asserting the Treatment Exchange Purpose, including the Level 2 XP Code TEFCA Required Treatment. Nothing in this SOP modifies the terms and conditions related to Treatment, as enumerated in the Exchange Purposes (XPs) SOP.

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   - 4.1 Exchange Purpose Code (XP Code)
   - 4.2 QHIN Technical Framework
   - 4.3 Definition
   - 4.4 TEFCA Transaction
5. TEFCA Required Treatment (T-TRTMNT)
   - 5.1 Exchange Purpose Code (XP Code)
   - 5.2 QHIN Technical Framework
   - 5.3 Definition
   - 5.4 TEFCA Transaction

Definitions

- **TEFCA Required Treatment:** means a Query for Treatment that all meets the requirements set forth in Section 5.3 of this SOP

- **Treatment:** has the meaning assigned to such term at 45 CFR § 164.50

5.3 TEFCA Required Treatment means:

- a) The following QHINs, Participants, or Subparticipants may initiate transactions using the TEFCA Required Treatment XP Code:
    - » i. Covered Entities that electronically transmit any health information in connection with transactions for which the Department of Health and Human Services (HHS) has adopted standards in the normal course of business and are one of the following types of Health Care Providers:
        - – 1. to the extent these terms are defined in 42 USC 1395(x): a Hospital; skilled nursing facility; nursing facility; home health entity; health care clinic; community mental health center; renal dialysis facility; blood center; ambulatory surgical center; emergency medical services provider; Federally Qualified Health Center; group practice; a pharmacist; a pharmacy; a laboratory; a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization (as defined in section 1603 of title 25); or, a rural health clinic; or

        - – 2. a natural person doctor of medicine or osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, chiropractor, or other natural person who is licensed, certified, registered, or otherwise authorized by a State to provide health care, including but not limited to, a physician assistant, nurse, nurse practitioner, social worker, psychologist, registered dietician or nutrition professional, physical therapist, occupational therapist, or speech-language pathologist (collectively, "Licensed Individual Provider").

    - » ii. The Veterans Health Administration, the Department of Defense, the Indian Health Service,t he National Oceanic and Atmospheric Administration, the Coast Guard, and other Government Health Care Entity(ies).

    - » iii. Delegates of the QHINs, Participants, and Subparticipants in Section 5.3(a)(i) and 5.3(a)(ii). Notwithstanding the foregoing, a Health Plan cannot be a Delegate of any QHINs, Participants, and Subparticipants in Section 5.3(a)(i) and 5.3(a)(ii) for purposes of initiating a Query using the TEFCA Required Treatment XP Code.

5.3 TEFCA Required Treatment means (continued):

- b) The TEFCA Required Treatment XP Code can only be asserted by a QHIN, Participant, or Subparticipant set forth in Section 5.3(a) if the Query is in connection with or intended to inform health care services that an entity in Section 5.3(a) is providing or intends to provide to a patient through synchronous or asynchronous interaction (either in-person or virtual) with a Licensed Individual Provider.

  - » i. This includes, but is not limited to, Querying for records: upon receipt of a notification of admission to or discharge from a hospital, for medication reconciliation and medication management; in support of care management; and for identification of care gaps all for an individual patient. Queries initiated using the TEFCA Required Treatment XP Code are intended to support health care services for individual patients. If a Query is made for a similar purpose at a population level, it is for Health Care Operations.

SOP: Delegation of Authority

Standard Operating Procedure
(SOP): Delegation of Authority

Version 1.0

July 1, 2024

Applicability: QHINs, Participants, Subparticipants

© 2024 The Sequoia Project

Purpose: This SOP identifies specific requirements that QHINs, Participants, and Subparticipants are required to follow when authorizing a Delegate to initiate Delegated Requests.

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   - 4.1 Overarching Requirements
   - 4.2 Delegated Requests
   - 4.3 RCE Directory Service
   - 4.4 QHIN Query
   - 4.5 Facilitated FHIR

Definitions

- **Delegate:** a First Tier Delegate or Downstream Delegate

- **Delegated Request:** a TEFCA Exchange Request initiated by a Delegate working, directly or indirectly, for a Principal

- **Delegation Notice:** the notice provided by a Participant or Subparticipant to its QHIN that the Participant or Subparticipant wants to authorize a Delegate to initiate Delegated Requests on behalf of the Participant or Subparticipant

- **Delegation Revocation:** the notice provided by a Participant or Subparticipant to its QHIN that the Participant or Subparticipant wants to remove a Delegate's authorization to initiate Delegated Requests on behalf of the Participant or Subparticipant

- **Downstream Delegate:** a QHIN, Participant, or Subparticipant that (i) is not acting as a Principal when initiating or Responding to a transaction via TEFCA Exchange and (ii) has a direct written agreement with a First Tier Delegate or another Downstream Delegate authorizing the respective Downstream Delegate to initiate or Respond to transactions via TEFCA Exchange for or on behalf of a Principal

- **First Tier Delegate:** a QHIN, Participant, or Subparticipant that (i) is not acting as a Principal when initiating or Responding to a transaction via TEFCA Exchange and (ii) has a direct written agreement with a Principal authorizing the First Tier Delegate to initiate or Respond to transactions via TEFCA Exchange for or on behalf of the Principal. For purposes of this definition, a "written agreement" shall be deemed to include a documented grant of authority from a government agency

Definitions (continued)

- **Initiating Node Only Attestation:** an attestation provided by a Participant or Subparticipant to its QHIN attesting the data obtained or created by the Participant's or Subparticipant's Initiating Node that becomes part of a Designated Record Set of a Principal is shared with another Responding Node that is identified in such attestation. For purposes of the Initiating Node Only Attestation, Designated Record Set has the meaning assigned to that term in 45 CFR §164.501 but applies to a Principal regardless of whether the Principal is a Covered Entity

- **Principal:** a QHIN, Participant or Subparticipant that is acting as a Covered Entity, Government Health Care Entity, NHE Health Care Provider, a Public Health Authority, a government agency that makes a Government Benefits Determination, or an IAS Provider (as authorized by an Individual) when engaging in TEFCA Exchange

SOP: Delegation of Authority

Key Highlights

- All Delegated Requests must list the Principal for whom the Delegate is initiating the Request

- QHINs must verify that transactions initiated by Delegates reference Principals listed in the RCE Directory Service in order to be accepted

- All QHINs, Participants, and Subparticipants must list any directly contracted Delegates in their Directory Entry(ies)

- A Delegation Notice must be provided for each Delegate listed in a Directory Entry

- Procedures for submitting and managing Delegation Notices require timely validation and updating of the RCE Directory Service

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

Standard Operating Procedure (SOP): RCE™ Directory Service (Directory) Requirements Policy

Version 1.0

July 1, 2024

Applicability: QHINs, Participants, and Subparticipants that control a Node

Purpose: This SOP describes RCE Directory Services (Directory) policy requirements that QHINs must follow when maintaining Directory Entries, in addition to the specifications set forth in the Framework Agreements, QTF, RCE Directory Service Implementation Guide, and applicable SOPs.

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   - 4.1 Requirements
   - 4.2 Example Diagram

Definitions

- **Delegate:** a First Tier Delegate or Downstream Delegate

- **Delegated Request:** a TEFCA Exchange Request initiated by a Delegate working, directly or indirectly, for a Principal

- **Downstream Delegate:** a QHIN, Participant, or Subparticipant that (i) is not acting as a Principal when initiating or Responding to a transaction via TEFCA Exchange and (ii) has a direct written agreement with a First Tier Delegate or another Downstream Delegate authorizing the respective Downstream Delegate to initiate or Respond to transactions via TEFCA Exchange for or on behalf of a Principal

- **First Tier Delegate:** a QHIN, Participant, or Subparticipant that (i) is not acting as a Principal when initiating or Responding to a transaction via TEFCA Exchange and (ii) has a direct written agreement with a Principal authorizing the First Tier Delegate to initiate or Respond to transactions via TEFCA Exchange for or on behalf of the Principal. For purposes of this definition, a "written agreement" shall be deemed to include a documented grant of authority from a government agency

Definitions (Continued)

- **Initiating Node Only Attestation:** an attestation provided by a Participant or Subparticipant to its QHIN attesting that data obtained or created by the Participant's or Subparticipant's Initiating Node that becomes part of a Designated Record Set of a Principal is shared with another Responding Node that is identified in such attestation. For purposes of the Initiating Node Only Attestation, Designated Record Set has the meaning assigned to that term in 45 CFR § 164.501 but applies to a Principal regardless of whether the Principal is a Covered Entity

- **Logical Entity**: a Participant or Subparticipant that is represented by one or more Nodes in the RCE Directory Service, all of which share a TEFCAID

- **Principal:** a QHIN, Participant or Subparticipant that is acting as a Covered Entity, Government Health Care Entity, NHE Health Care Provider, a Public Health Authority, a government agency that makes a Government Benefits Determination, or an IAS Provider (as authorized by an Individual) when engaging in TEFCA Exchange

- **Transaction Type(s):** any one of a Patient Discovery, Document Query, Document Retrieval, Message Delivery, and/or FHIR

Initiating Node of a Principal Must Also Be a Responding Node

A Node that is an Initiating Node of a Principal MUST meet one of the following two requirements unless another exception applies:

i.   Be a Responding Node; or
ii. Be hierarchically below a Responding Node for Document Retrieval where such Responding Node is sharing all Required Information from a downstream Participant or Subparticipant that would otherwise be provided by the Participant or Subparticipant's Initiating Node, if the Initiating Node were a Responding Node.

Scenario 1 — Scenario 2

Legend:
- Initiating Node
- Responding Node
- Initiating and Responding Node
- Passthrough Node
- Principal
- Delegate
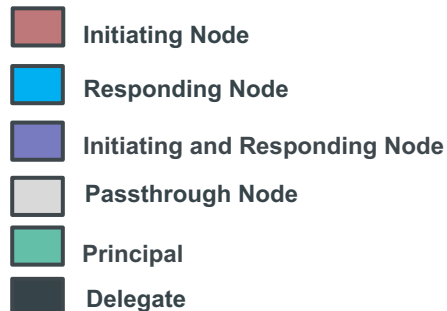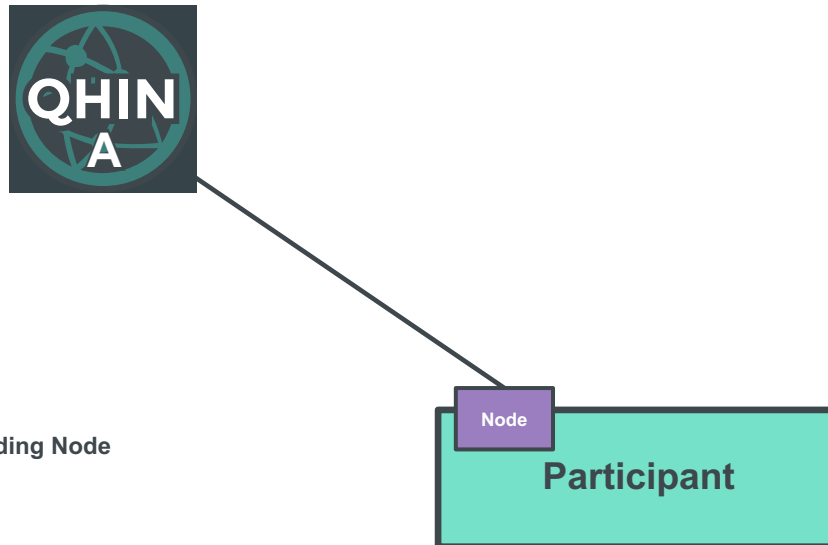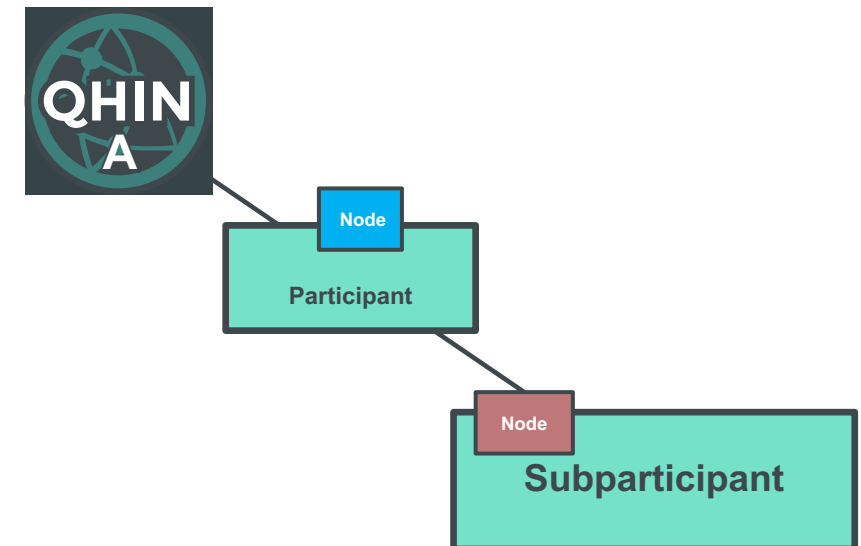
Delegates

For Delegates, if the Delegate is exempted from required Response pursuant to the XPs SOP, then the Delegate's Initiating Node is not required to be or have an associated Responding Node.

XPs SOP: Responding Nodes of Delegates MUST Respond to Requests for the XP Codes listed in Table 2 as having a required Response, if authorized by the written agreement authorizing the Delegate to conduct TEFCA Exchange for the Principal, except to the extent that one or more of the exceptions applies as set forth in Section 4.6 of this SOP.

- **Initiating Node Only**
- **Responding Node Only**
- **Initiating and Responding Node**
- **Passthrough Node**
- **Principal**
- **Delegate**
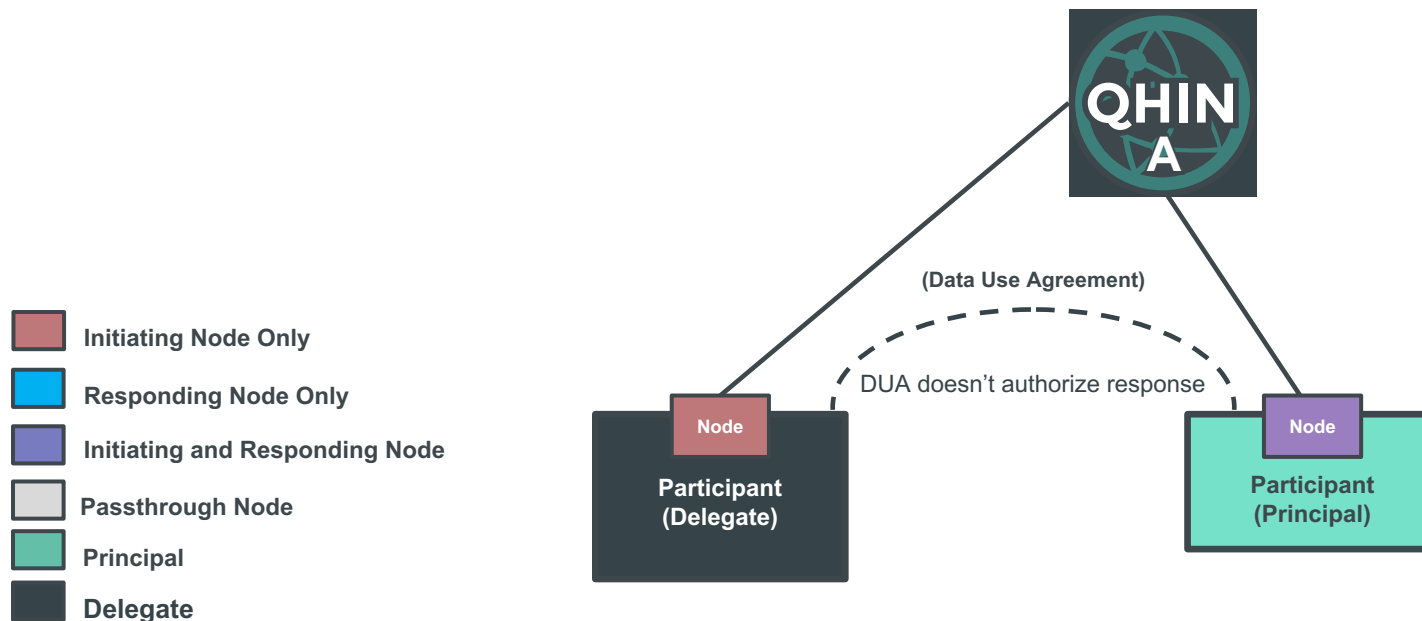
DUA: Data use Agreement

TEFCAID

- A Logical Entity with multiple Nodes MUST have the same TEFCAID shared across each of its Nodes.
  - » a) QHINs MUST work with their Participants and Subparticipants during onboarding to determine whether any new Directory Entry is affiliated with an existing Logical Entity that has been assigned a TEFCAID.
    - – i. When a new Directory Entry is affiliated with an existing TEFCAID, the publishing QHIN MUST submit its new Directory Entry with that TEFCAID listed. The RCE Directory Service will:
      - 1. Validate the TEFCAID submitted to ensure the TEFCAID already exists.
      - 2. Where it does not exist, an RCE Directory Service validation error will be returned, allowing the QHIN to make a correction.
    - – ii. When a new Directory Entry is not affiliated with an existing TEFCAID, the publishing QHIN MUST NOT submit any value for TEFCAID. The RCE Directory Service will:
      - 1. Assign and populate a new unique TEFCAID.

Standard Operating Procedure (SOP): Individual Access Service (IAS) Provider Requirements

Version 2.0

July 1, 2024

Applicability: QHINs, Participants, and Subparticipants that offer Individual Access Services

Purpose: IAS Providers are required to obtain the Individual's express documented consent in connection with IAS via a written Privacy and Security Notice.

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   - 4.1 Written Privacy and Security Notice and Individual Consent
   - 4.2 Consent to Sale
   - 4.3 Content of Notice to Individual of TEFCA Security Incident or Breach of Unencrypted Information (IAS Incident)

Definition:

- **Material Change(s) to the Notice:**
  - *"a change to the Privacy and Security Notice that results in the Use and Disclosure of Individually Identifiable Information by the IAS Provider in a different manner than when the Individually Identifiable Information was collected or otherwise obtained…"*

IAS Privacy and Security Notice
- An IAS Provider must obtain the Individual's express documented consent in connection with IAS, including acknowledgment of and agreement to the IAS Provider's written Privacy and Security Notice ("Notice") that describes the privacy and security practices used to safeguard Individually Identifiable Information

Consent to Sale
- If an IAS Provider intends to 1) sell, 2) receive remuneration in exchange for Individually Identifiable Information, or 3) use Individually Identifiable Information for targeted advertising or other marketing purposes, the IAS Provider must obtain the Individual's prior, express, and documented consent
- Consent to Sale may be obtained with the consent to the Notice but must be labeled as such and separate from the consent to the Notice

Content of Notice to Individual of TEFCA Security Incident or Breach of Unencrypted Information
- Brief description of what happened
- Description of the type of Individually Identifiable Information involved
- Steps Individuals should take to protect themselves
- Brief description of what the IAS Provider is doing to investigate, mitigate and protect against further incidents
- Contact procedures

SOP: Governance Approach

Standard Operating Procedure (SOP): Governance Approach

Version 1.0

July 1, 2024

Applicability: QHINs, Participants, Subparticipants

© 2024 The Sequoia Project
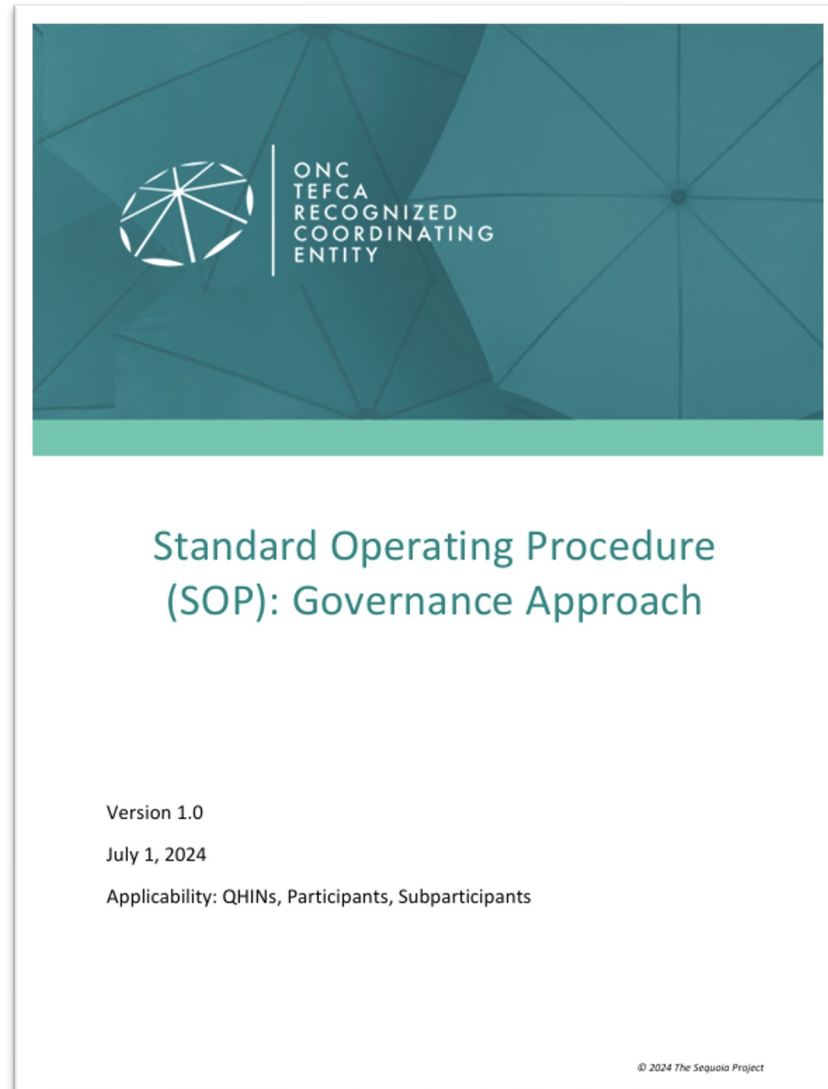
Purpose: This SOP sets forth the formation, composition, responsibilities and duration of the Transitional Council and the Governing Council. It requires the RCE to establish a Transitional Council and then a Governing Council responsible for serving as a resource to the RCE and governing body for activities conducted under the Framework Agreements

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   - 4.1 Participation in Governance
   - 4.2 Transitional Council

SOP: Governance Approach

Key Highlights:

- The Transitional Council serves as the interim governing body for the activities conducted under the Framework Agreements

- The Transitional Council is developing the transition plan to the Governing Council, which will serve as the permanent Governing body

- The Transitional Council will develop a QHIN Caucus and a Participant/Subparticipant Caucus, which will provide feedback and vote on updates to the Framework Agreement, SOPs, and QTF

Transitional Council / Governing Council

- QHIN Caucus
- Participant/ Subparticipant Caucus
- Advisory Groups
- Cybersecurity Council
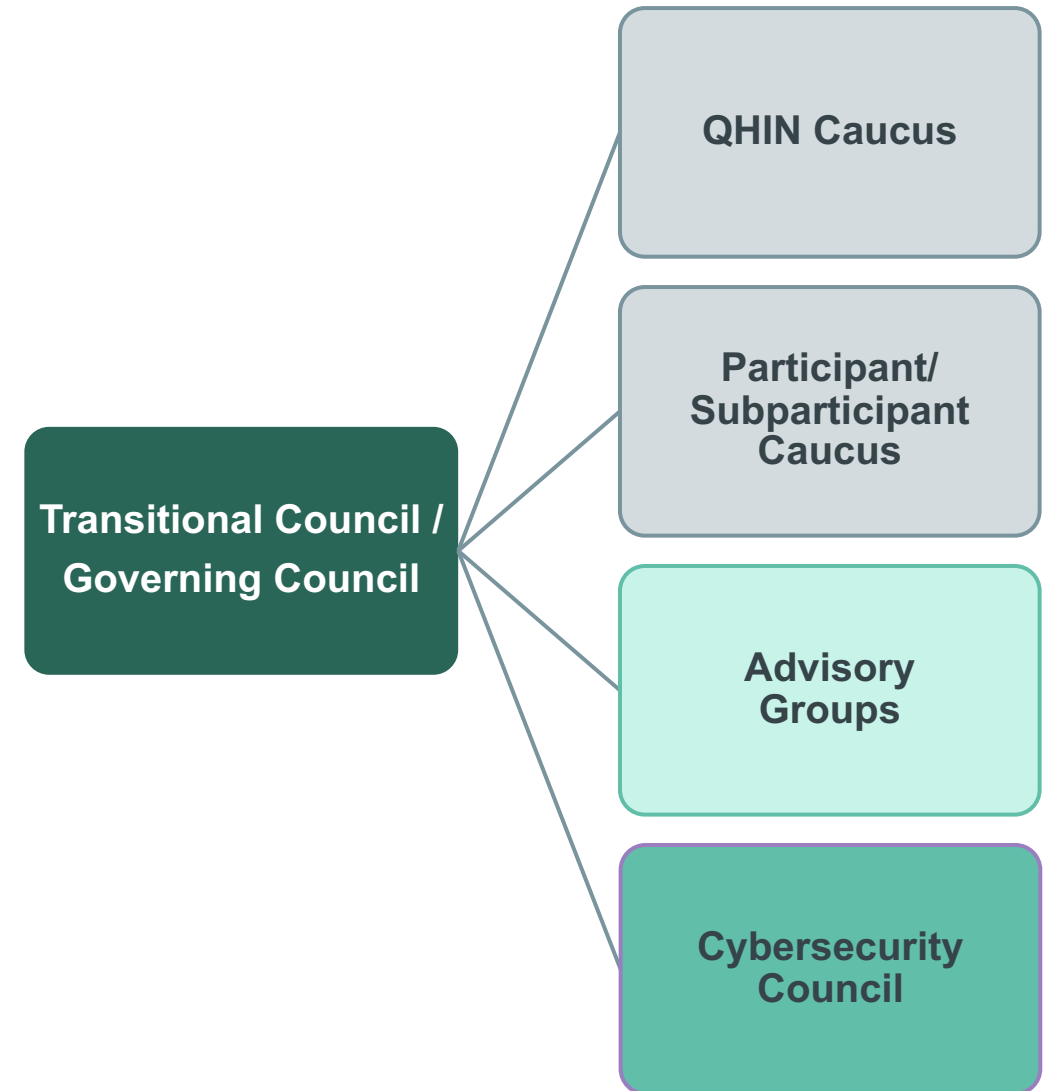
SOP: Expectations for Cooperation

Standard Operating Procedure (SOP): Expectations for Cooperation

Version 1.0

July 1, 2024

Applicability: QHINs, Participants, Subparticipants

© 2024 The Sequoia Project

Purpose: Section 6.1 of the Common Agreement and Section 2.1 of the Participant/Subparticipant Terms of Participation requires QHINs, Participants, and Subparticipants to reasonably cooperate with the RCE, ONC, other QHINs, and their representative Participants and Subparticipants in all matters related to TEFCA Exchange. This SOP sets forth the expectations for reasonable cooperation.

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   - n/a

SOP: Expectations for Cooperation

Key Highlights:

- To the extent not in violation of Applicable Law, each QHIN, Participant, and Subparticipant MUST:
  - Respond in a timely manner to inquiries from the RCE or an Upstream QPS
  - Participate collaboratively in discussions coordinated by the RCE and/or Upstream QPS
  - Make reasonable efforts to notify the RCE, Upstream QPS, and other QHINs when persistent and/or widespread connectivity failures are occurring
  - Work collaboratively to address the root cause(s) of persistent and/or widespread connectivity failures
  - Provide relevant information to address reasonable questions regarding the Exchange Purpose represented in a transaction
  - Work cooperatively when presented with objective, verifiable documentation that a QHIN's Participants or Subparticipants are inappropriately utilizing TEFCA Exchange
  - Provide information in support of collaborative efforts to resolve issues or Disputes
  - Provide information to understand, contain, mitigate, or fulfill reporting or notification obligations arising from a TEFCA Security Incident or Breach of Unencrypted Individually Identifiable Information
  - Disclose information to the RCE that relates to information shared through cybersecurity risk information sharing programs or information related to a Threat Condition

Upstream QPS: participates in TEFCA by providing technical and/or governance services to its Participants and/or Subparticipants to facilitate their ability to engage in TEFCA Exchange consistent with all applicable legal and contractual requirements.
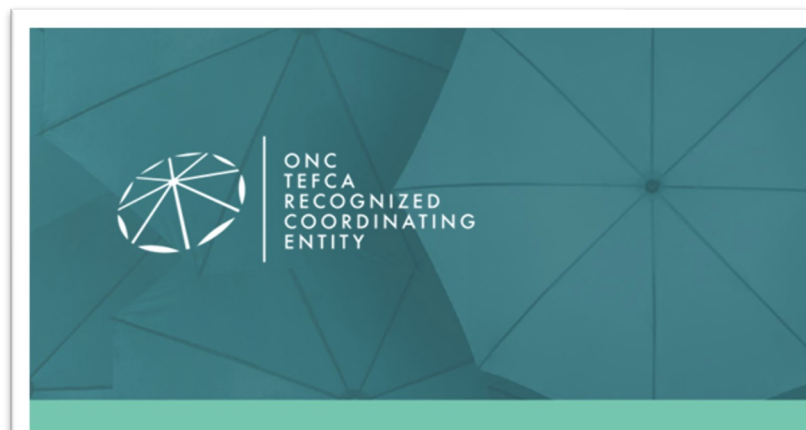
Standard Operating Procedure (SOP): TEFCA Security Incident Reporting

Version 1.0

Date: July 1, 2024

Applicability: RCE, QHINs, Participants, Subparticipants

© 2024 The Sequoia Project

Purpose: This SOP details the minimum reporting requirements for communicating TEFCA Security Incidents to the RCE, to other likely impacted QHINs, and to any likely impacted Participant and/or Subparticipant within the QHIN's network, as set forth in the Common Agreement and Terms of Participation.

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   - 4.1 Confidentiality of Reports
   - 4.2 General TEFCA Security Incident Reporting Requirements
   - 4.3 TEFCA Security Incident Reporting for QHINs
   - 4.4 TEFCA Security Incident Reporting Requirements for Participants and Subparticipants
   - 4.5 TEFCA Security Incident Reporting Requirements for RCE
   - 4.6 TEFCA Security Incident Report Format
5. Informative Guidance: TEFCA Security Incident Determination
   - 5.1 Factor A: Did the incident involve TEFCA Information?
   - 5.2 Factor B: Is there a permitted exception?
   - 5.3 Factor C: Is the incident considered an other reportable security event?

SOP: TEFCA Security Incident Reporting

QHIN Reporting for TEFCA Security Incidents		
Report Type	**Timeline**	**Distribution**
QHIN TSI Initial Report	As soon as reasonably practicable, but not more than 72 hours after Discovery	1) If a QHIN experiences a TSI, or receives a TSI report from a downstream Participant or Subparticipant that is confirmed to be a TSI, it reports to the RCE using the TEFCA Security Incident Report form and 2) to all other QHINs likely impacted, and to Participants and Subparticipants within the reporting QHIN's network that are likely impacted.
QHIN TSI Supplemental Report	As additional pertinent information becomes available, and at least every 24 hours until the incident is resolved	Same as above for an initial TSI report
QHIN TSI Post-Incident Report	Required within 30 days after incident has been resolved	Affected QHIN reports to the RCE

Participant/Subparticipant Vertical Reporting for TEFCA Security Incidents		
Report Type	**Timeline**	**Distribution**
Vertical Reporting by Participants and Subparticipants.	For the Discovering entity: As soon as reasonably practicable, but not more than 72 hours after Discovery For the entity receiving a report from another entity: When vertically reporting a TEFCA Security Incident, the receiving entity has one business day to forward the report to their upstream entity and to likely affected downstream entities	1) To Upstream QPS any suspected or actual TEFCA Security Incident, and 2) To any likely affected Downstream Subparticipant for any actual TEFCA Security Incident they experience or has been reported to them by their Upstream QPS

Other Reportable Security Events are those security-related events that adversely affect a QHIN's, Participant's, or Subparticipant's participation in TEFCA Exchange, such as ransomware attacks.
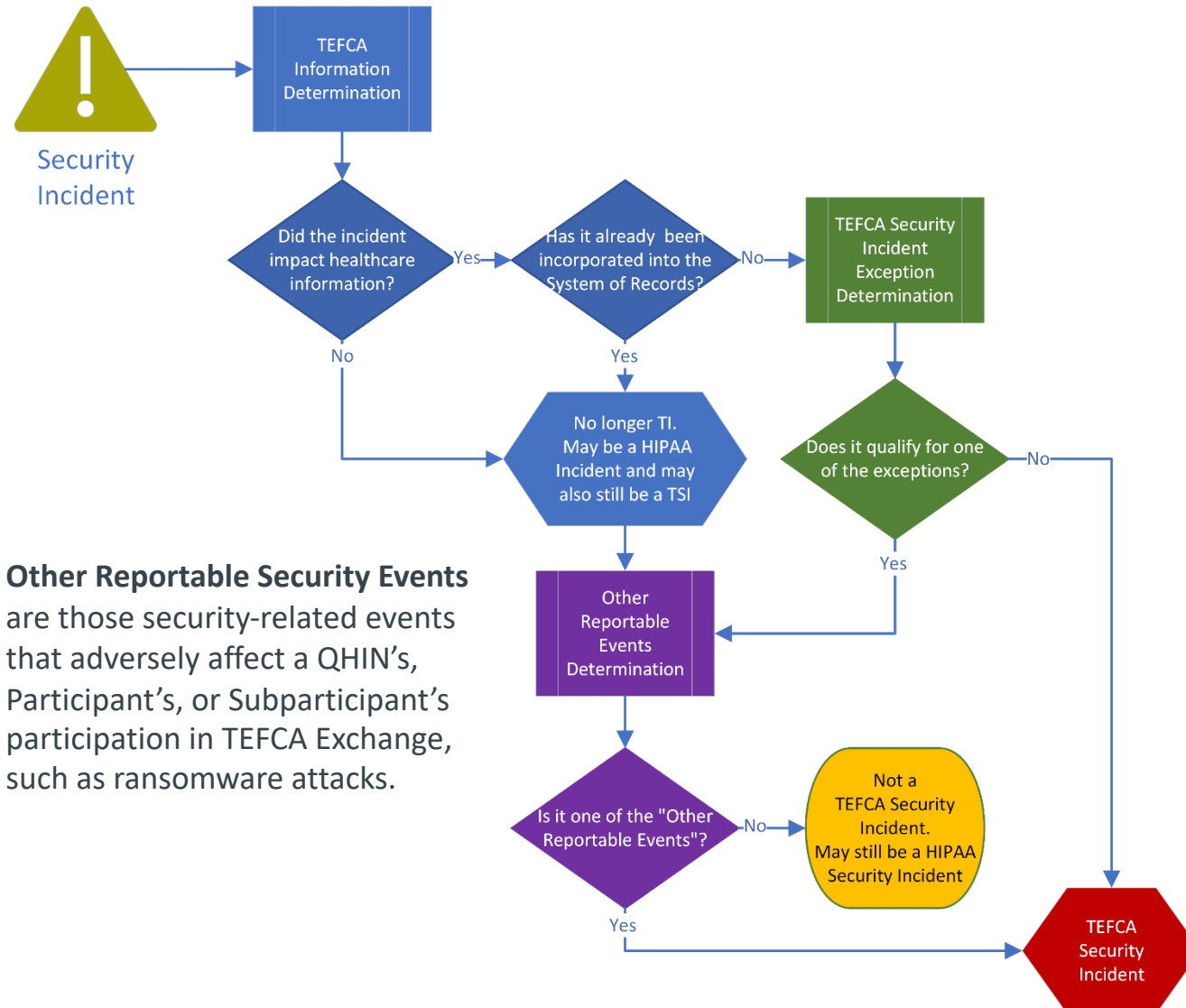
EXCEPTIONS: An unauthorized acquisition, access, Disclosure, or Use of unencrypted TEFCA Information using TEFCA Exchange, is **NOT** a TEFCA Security Incident if **ANY** of the exceptions (a) through (c) apply:

(a) An unintentional acquisition, access, Use, or Disclosure of TEFCA Information by a Workforce Member or person acting under the authority of a QHIN, Participant, or Subparticipant, if such acquisition, access, Use, or Disclosure;
   (i) was made in good faith,
   (ii) was made by a person acting within their scope of authority,
   (iii) was made to another Workforce Member or person acting under the authority of any QHIN, Participant, or Subparticipant, and,
   (iv) does not result in further acquisition, access, Use, or Disclosure in a manner not permitted under Applicable Law and the Framework Agreements.

(b) A Disclosure of TI where a QHIN, Participant, or Subparticipant has a good faith belief that an unauthorized person to whom the Disclosure was made would not reasonably have been able to retain such information.

(c) A Disclosure of TI that has been de-identified in accordance with the standard at 45 CFR § 164.514(b).

Technical Document Updates:
(QHIN) Technical Framework (QTF) and FHIR Implementation SOP
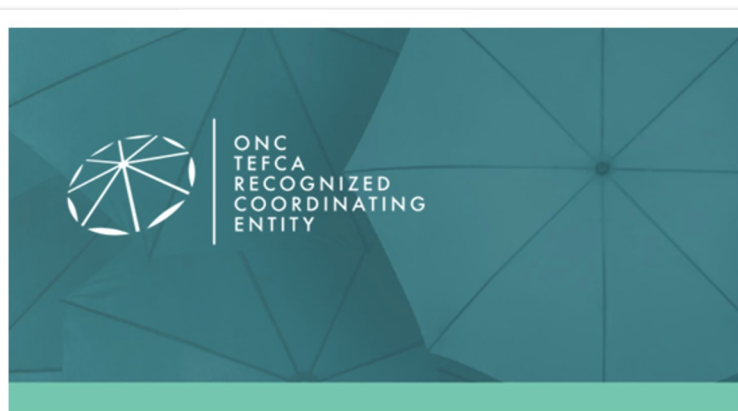
Trusted Exchange Framework and Common Agreement

Qualified Health Information Network (QHIN) Technical Framework (QTF)

Version 2.0

© 2024 The Sequoia Project

Purpose: The QHIN Technical Framework (QTF) describes the functional and technical requirements that a Health Information Network (HIN) must fulfill to serve as a QHIN. The QTF specifies the technical underpinnings for TEFCA Exchange, QHIN technical capabilities and services, and certain other responsibilities, some of which flow down to Participants and Subparticipants.

Table of Contents

- Overview
- QHIN Exchange Scenarios
- Requirements for Functions and Technology to Support Exchange
- Constraints Specific to Facilitated FHIR Exchange
- Testing Procedure Supporting Requirements
- Performance Measures

QHIN Technical Framework (QTF) Version 2.0

Key Changes from Version 1.1
- Specified use of FHIR R4 Version 4.0.1; implementation specifics are defined in the FHIR Implementation SOP
- Moved XP Codes to Exchange Purposes (XPs) SOP
- Clarified ATNA requirements to require QHINs to be able to export all relevant information as specified in ATNA

Required Information
- Data created or captured and sent on or after December 31, 2024 SHOULD conform to data classes, data elements, and vocabulary requirements in USCDI V1 or later. Legacy data captured and sent prior to December 31, 2024 MAY conform to USCDI data classes, data elements, and vocabulary requirements in USCDI V1 or later.
  - » As of January 1st, 2026, all information sent MUST conform to USCDI V3 data classes, data elements, and vocabulary requirements.
  - » Where no code matching a data requirement exists in a USCDI specified code system, a code from a recognized code system (e.g., ICD-10, LOINC) SHOULD be used or a custom code MAY be used.

Standard Operating Procedure (SOP): Facilitated FHIR Implementation

Version 1.0

July 1, 2024

Applicability: QHINs, Participants, Subparticipants that engage in TEFCA Exchange leveraging Facilitated FHIR

© 2024 The Sequoia Project
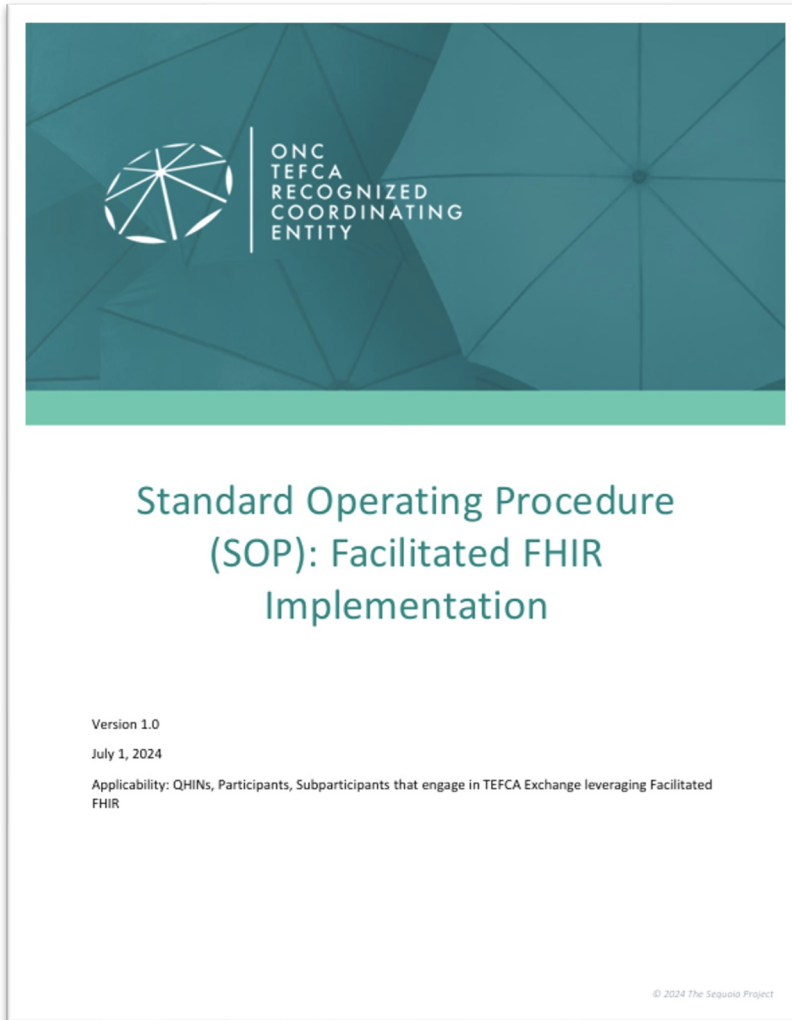
Purpose: This SOP identifies specific requirements for Facilitated FHIR implementation activities. Any FHIR Adopter may participate in any of the FHIR activities specified in this SOP. This SOP provides a roadmap that allows for a transition period to ease adoption of an eventual network-wide approach.

Table of Contents

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Facilitated FHIR Query Scenario
5. Use Case Steps
6. Procedure

FHIR Security Roadmap

Requirements for registration, authentication, and authorization of FHIR clients MUST follow these requirements:

a. **Prior to January 1, 2026** :

 i. All FHIR Adopters MAY follow the requirements of HL7 FAST Security IG 1.0.0 (SSRAA) Registration process

 1. Manual registration requests MUST be resolved within 5 days where sufficient information has been provided. Information requirements MUST NOT exceed those of SSRAA and this SOP.

 ii. All FHIR adopters MUST use one of the following:

 1. SSRAA Authentication and Authorization sections

 2. SMART Release 1.0.0; or

 3. Another authentication and authorization framework that adheres to QTF requirements and based on out-of-band agreements between exchange partners.

b. **Beginning January 1, 2026**, all FHIR Adopters MUST follow SSRAA for registration, authentication and authorization

1. Prior to January 1, 2026, FHIR Adopters MAY determine their own exchange partners. FHIR Adopters will be responsible for coordinating directly with each other to identify which FHIR Adopters have (1) a compatible registration approach and (2) a compatible approach to patient discovery.

2. Beginning January 1, 2026, all FHIR Adopters MUST follow the requirements in HL7 SSRAA FHIR IG 1.0.0 – STU 1 US Sections 2, 3, 4, and 5.

3. A FHIR Implementation Advisory Group is being established to track progress towards Implementation.

Educational Resources and Upcoming Events

TEFCA Glossary and Cross Reference Resource

The TEFCA Glossary is intended to serve as an in-depth compilation of terms and their definitions referenced in the Common Agreement Version 2.0, QTF Version 2.0, Participant/Subparticipant Terms of Participation (ToP) Version 1.0, and the SOPs.

The TEFCA Cross Reference Resource is intended to help QHINs, Participants, and Subparticipants, understand which SOPs are relevant to which sections of the applicable Framework Agreements.

PLEASE NOTE THAT WHILE WE STRIVE TO MAINTAIN ACCURACY IN THIS RESOURCE, IT IS PROVIDED FOR EDUCATIONAL PURPOSES ONLY. THIS RESOURCE SHOULD NOT BE SOLELY RELIED UPON BY QHINS, PARTICIPANTS, OR SUBPARTICIPANTS. IT IS ULTIMATELY A QHIN'S, PARTICIPANT'S, OR SUBPARTICIPANT'S CONTRACTUAL RESPONSIBILITY TO ENSURE IT IS COMPLIANT WITH ALL APPLICABLE SOPS REGARDLESS OF WHETHER THEY ARE LISTED IN THIS RESOURCE.

RCE Resource Library

TEFCA is a multifaceted, living framework that enables seamless and secure nationwide exchange of health information.

GETTING STARTED
↓

Below is a guide to the Common Agreement, Standard Operating Procedures (SOPs), technical documents, and other resources that make up TEFCA's rules of the road. Start your journey to next generation interoperability here.

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

Additional Resources:
https://www.healthit.gov/tefca

All Events Registration and Recordings:

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

Upcoming RCE Monthly Info Calls:
August 20th, 12:00pm ET
September 17th, 12:00pm ET

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

Questions & Answers

For more information:
rce.sequoiaproject.org