



ONC  
TEFCA  
RECOGNIZED  
COORDINATING  
ENTITY

# Standard Operating Procedure (SOP): QHIN Onboarding & Designation

Version 3.0 (updated as of January 2025)

Applicability: RCE; Entities seeking to be Designated as a QHIN

## 1. COMMON AGREEMENT REFERENCES

The Common Agreement addresses the Designation of Qualified Health Information Networks® (QHINs™). The Common Agreement requires anyone seeking to be designated as a QHIN to demonstrate that it meets the QHIN eligibility criteria.

The requirements set forth in this SOP are the basis for the questions posed in the QHIN Application. Adherence to this SOP is required for Designation in addition to the terms and conditions found in the Common Agreement, the QHIN Technical Framework (QTF), and applicable SOPs. The TEFCA™ Cross-Reference Resource identifies which SOPs provide additional detail on specific references from the Common Agreement.

All documents cited in this SOP can be found on the [RCE website](#).

## 2. SOP DEFINITIONS

Terms defined in this section are introduced herein and can be found in the TEFCA Glossary. Other capitalized terms used in this SOP without definition shall have the respective meanings assigned to such term in the TEFCA Glossary.

**Applicant or Applicant QHIN:** means any organization that has submitted an intent to apply to be a QHIN to the Recognized Coordinating Entity® (RCE®), and that intent to apply has been accepted by the RCE, as specified in this SOP. The organization will no longer be deemed an Applicant if it withdraws that intent to apply, it does not submit a completed application within ninety (90) days, or if its intent to apply is otherwise terminated by the RCE. Applicant also includes those organizations that have submitted a QHIN Application to the RCE for completeness review as set forth in this SOP, and that application has not been withdrawn or otherwise terminated.

**Candidate or Candidate QHIN:** means any organization that has been notified by the RCE that its QHIN Application has been accepted to continue to the testing and project plan phase as set forth in this SOP.

**Onboarding:** the process Applicant must undergo to become a Designated QHIN, as set forth in this SOP.

The following definitions are defined in the Common Agreement and repeated here for reference.

**Designated Network:** the Health Information Network that a QHIN uses to offer and provide the Designated Network Services.

**Designated Network Services:** the Connectivity Services and/or Governance Services [used for TEFCA Exchange].

**Common Agreement (CA) Effective Date:** if (i) Signatory was Designated as a QHIN prior to the Implementation Date, then the Implementation Date; or (ii) if Signatory was Designated as a QHIN after the Implementation Date, then the date that the RCE executes the Common Agreement to which Signatory is a Party.

### 3. PURPOSE

This SOP identifies the process and specific requirements for Onboarding and Designation of QHINs, including demonstrating satisfaction of the QHIN eligibility criteria, the review and disposition of all QHIN Applications, and the testing process.

### 4. COMMUNICATION OF ONBOARDING & DESIGNATION STATUS BY APPLICANT

By submitting an intent to apply for QHIN Designation, the Applicant agrees that it will only communicate its status at any point during this Onboarding & Designation process in accordance with the RCE's Communications Protocols, available at <https://rce.sequoiaproject.org/tefca-and-rce-resources/>.

### 5. PROCEDURE

The RCE may extend all time periods in this SOP that apply to the RCE upon notice to the Applicant, Candidate, or Designated QHIN, as applicable. The RCE may, at its sole discretion, extend time periods that apply to an Applicant, Candidate, or Designated QHIN if the organization provides the RCE with written, factual, and verifiable information that supports providing the organization with additional time to meet the applicable requirement(s) in question.

#### 5.1 Eligibility Requirements

Applicants must satisfy the eligibility criteria set forth in the Common Agreement, including the requirements for the satisfaction of each criterion as set forth in this SOP. A Designated Network may be a standalone Health Information Network or part of a pre-existing Health Information Network.

Applicant may operate an established Health Information Network or it may be a wholly-owned subsidiary of a parent entity (“Parent”) that operates an established Health Information Network (“Parent’s Current Network”). In the event Applicant is a subsidiary of a Parent and Applicant does not itself meet the eligibility criteria, Applicant may meet the requirement by providing information related to Parent and Parent’s Current Network in response to those eligibility criteria marked with an “\*”. If Applicant does not provide information about itself and its current Health Information Network(s) nor its Parent and Parent’s Current Network, Applicant will be deemed to have not met the applicable eligibility criteria. For the avoidance of doubt, if a requirement is not marked with an “\*”, then Applicant must demonstrate that Applicant meets the requirement itself without reliance on Parent or Parent’s Current Network.

**1. Common Agreement Criterion: “Signatory is a U.S. Entity and is not controlled by any person or entity that is not a U.S. Qualified Person(s) or U.S. Entity(ies). The specific, required means to demonstrate this are set forth in an SOP.”**

- a) At the time of application, Applicant must provide a copy of its charter or equivalent document issued by the Secretary of State, or similar government agency, for the U.S. jurisdiction in which the Applicant is legally organized or incorporated. Applicant shall provide its principal place of business, which shall be within the United States.
- b) At the time of application, Applicant must provide a certificate of good standing, or similar document, issued and certified by the relevant governmental authority for the jurisdiction in which Applicant is domiciled and dated within ninety (90) calendar days of the date of Applicant’s QHIN Application.
- c) At the time of application, Applicant must provide a current copy of its organizing documents, such as Articles of Incorporation and Bylaws for a corporation or Articles of Organization and Operating Agreement for a limited liability company. Applicant must attest that the documents submitted are current and complete.
- d) At the time of application, Applicant must complete the Means to Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire. Prior to application approval, Applicant must not be disqualified pursuant the Means to Demonstrate U.S. Ownership and Control of a QHIN SOP, and, if applicable, must receive a determination that Applicant is not under Foreign Control (as defined in the Means to Demonstrate U.S. Ownership and Control of a QHIN SOP).

**2. Common Agreement Criterion: “Signatory is a Health Information Network.”**

- a) At the time of application, Applicant must meet directly, or indirectly through its Parent, the following:
  - (i) \*Applicant must describe the purposes for exchange that are currently permitted on its current network, which must include at least one of the Exchange Purposes (XPs) or a substantially similar purpose;

- (ii) \*Applicant must be capable of exchanging information among more than two unaffiliated organizations and describe the number and types of entities that exchange information through its current network, including their affiliation or non-affiliation with one another; and
  - (iii) \*Applicant must describe the type of information that is currently exchanged through its current network (e.g., electronic protected health information (ePHI), Designated Record Set), which must include at least some clinical data.
- b) Be capable of (i) receiving and responding to transactions from other QHINs for all of the XPs; and (ii) initiating transactions for the XPs that Applicant will permit its Participants and Subparticipants to send through its Designated Network. Alternatively, if Applicant is not capable of (i) or (ii) at the time of application, the Applicant may demonstrate (i) and (ii) by submitting a project plan and completing such project plan prior to beginning the testing required in Section 5.3 of this SOP.
- c) Prior to Designation, Applicant must be a Health Information Network in its own right, meeting all the preceding requirements without relying on the Parent or Parent's Current Network.

**3. Common Agreement Criterion: "Signatory has the ability to perform all of the Designated Network Services and other required functions of a QHIN in the manner required by this Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE. The specific, required means to demonstrate this are set forth in an SOP(s)".**

It is anticipated that QHINs may process tens of millions of transactions each day. To help ensure the success of the Common Agreement, all QHINs must demonstrate their experience and ability to operate a high-performing network with query capability.

a) High Performing Network:

- (i) \*At the time of application, Applicant must demonstrate that its current network performs at least one (1) million transactions<sup>1</sup> per day.
- (ii) At the time of application, Applicant must provide specific information regarding its current network (or Parent's Current Network) architecture, and its Designated Network architecture. Applicant must provide details in the project plan on how it will scale to keep pace with the volume of transactions required to support the Designated Network, which could reach fifty (50) million transactions or more per

---

<sup>1</sup> Current network transactions include transactions that are between the Applicant (or Parent) and external entities, including between Applicant (or Parent) and its participants within its current network (or Parent's Current Network).

day. Details must include the additional technical capacity, staff, and other resources needed to scale.

b) Experience supporting query transactions:

- (i) \*At the time of application, Applicant must provide specific evidence of its current network having been in operation and being capable of exchanging all Required Information by supporting either (i) the query functionality, as outlined in the QHIN Technical Framework (QTF),<sup>2</sup> for at least the twelve (12) consecutive calendar months immediately preceding submission of its application to be Designated as a QHIN, or (ii) the transmission of Required Information using a different but functionally comparable exchange method<sup>3</sup> to the QTF in a live production environment for at least the twelve (12) consecutive calendar months immediately preceding its application to be Designated as a QHIN (collectively i and ii are the “Historic Experience”).
- (ii) At the time of application, Applicant must provide a description of how the Historic Experience and resources used in connection with the Historic Experience will be leveraged in connection with the Designated Network if it is different from the Applicant’s current network (or Parent’s Current Network).

c) At the time of application, Applicant must identify any gaps between its current technical infrastructure and the applicable requirements of the QTF and identify its plan to address these gaps in its project plan so that Applicant’s Designated Network will be able to fully comply with the QTF prior to beginning the testing required in Section 5.3 of this SOP.

d) Following approval of the application but prior to Designation, Applicant must provide evidence of its Designated Network’s compliance with the applicable provisions of the QTF, including but not limited to any required conformance, interoperability, or partner testing as specified in this SOP and/or in the separate QHIN Testing Process document(s).

**4. Common Agreement Criterion: “Signatory has in place the organizational infrastructure and legal authority to comply with the obligations of the Common Agreement and to provide Governance Services for its Designated Network. In addition, Signatory has the resources and infrastructure to support a reliable and trusted network. The specific, required means to demonstrate this are set forth in an SOP(s).”**

---

<sup>2</sup> Query functionality as outlined in the QTF means executing all functions in Table 1 of the QTF using the specified standards for each function in said Table.

<sup>3</sup> [F]unctionally comparable exchange method means executing all of the functions specified in Table 1 of the QTF, using either (i) standards (including proprietary standards) other than those specified Table 1 or (ii) a combination of standards other than those specified in Table 1 and standards specified in Table 1. [F]unctionally comparable exchange method does not require experience using specific standards or profiles.

- a) QHINs must have a representative and participatory group or groups that approve the written processes for fulfilling the Governance Functions (Governance Functions Policies) and participate in such Governance Functions for the Designated Network. This group(s) is referred to as the Designated Network Governance Body. For purposes of this SOP, Governance Functions refer to those functions, activities, and responsibilities set forth in Section 5.1(4)(g) of this SOP. The Designated Network Governance Body will be considered representative and participatory if it meets the requirements set forth in Section 5.1(4)(f) of this SOP.
- b) \*At the time of application, Applicant must submit a detailed description of how it governs its current network. This description must include a description of the individual/group responsible for governing its current network, how the governance is performed, and evidence of the legal authority supporting such governance.
- c) At the time of application, Applicant must submit a detailed description of how the Governance Functions for its Designated Network set forth in Section 5.1(4)(g) of this SOP will be fulfilled. This must include a description of the Designated Network Governance Body, how the Governance Functions will be performed, and how the Designated Network Governance Body will comply with the requirements set forth in Section 5.1(4)(f) and 5.1(4)(g) of this SOP.
- d) At the time of application, the Applicant must submit documentation that the Designated Network Governance Body has the authority to approve the Governance Functions Policies and participate in such Policies in a manner that meets the requirements of this SOP. If the Designated Network Governance Body is not the same as Applicant's corporate governing body (e.g., board of directors), Applicant's submission must include documentation from the corporate governing body recognizing the authority of the Designated Network Governance Body to approve the Governance Functions Policies and participate in those Policies in a manner that meets the requirements of this SOP. This documentation may include bylaw provisions, board minutes, a unanimous consent, an attestation from the board secretary that such action was taken at a meeting of the board, or other evidence that appropriately documents such authority. If the Designated Network Governance Body is the same as Applicant's corporate governing body, documentation must include documentation from the corporate governing body that it has reserved the authority to approve the Governance Functions Policies and participate in such Policies in a manner that meets the requirements of this SOP.
- e) Applicant must provide the documentation described in Section 5.1(4)(e) (the Operational Documentation). Applicant must provide the Operational Documentation at the time of application if Applicant has such Operational Documentation. If Applicant does not have such Operational Documentation, then in its project plan, Applicant must explain the steps it is taking to create such Operational Documentation and the timelines for doing so. Such Operational Documentation must



- be provided prior to Designation. Operational Documentation must include the following:
- (i) The legal agreement, including the Terms of Participation (ToP), between Applicant and a Participant in the Designated Network that Applicant uses to enforce the policy, technical, and legal requirements of its Designated Network with its Participants. If Applicant does not have a network legal agreement, the burden is on Applicant to demonstrate that it does have a legally enforceable approach.
  - (ii) Process by which Applicant evaluates organizations to decide that they have the necessary technical, legal, and operational capability to participate in Applicant's Designated Network (e.g., onboarding policy).
  - (iii) Technical Framework Policy, Dispute Resolution Policy, Data Breach Response Policy, Participant Enforcement Policy, and Change Management Policy (collectively, the Governance Functions Policies).
- f) Applicant's Designated Network Governance Body must be representative and participatory. To be deemed representative and participatory, the Designated Network Governance Body must include the following:
- (i) Representatives of Applicant's Participants and Subparticipants must be voting members in Applicant's Designated Network Governance Body and must represent the diversity of Participants and Subparticipants in Applicant's Designated Network.
  - (ii) Participant and Subparticipant representative(s) must be able to constitute a quorum of the Designated Network Governance Body (the Quorum Requirement). A quorum of the Designated Network Governance Body must also require the presence of Participant or Subparticipant representative(s). Applicant must require that actions taken by the Designated Network Governance Body without meetings require at least one Participant or Subparticipant vote(s).
    - a. Notwithstanding the Quorum Requirement, a QHIN may require the presence of one non-voting QHIN staff member at a meeting of the Designated Network Governance Body. Neither Applicant nor such staff member may use the staff member's absence to inappropriately prevent the Designated Network Governance Body from meeting. The documentation provided in response to Section of this SOP, which establishes the Designated Network Governance Body, must include: (1) eligibility criteria for Participant and Subparticipant representative(s), (2) the number (or range) of individuals that participate on the Designated Network Governance Body, (3) the number (or range) of Participant and



Subparticipant representative(s), (4) the minimum frequency with which meetings of the Designated Network Governance Body are required to take place (e.g., monthly, quarterly, etc.), and (5) if applicable, the relationship to the existing Applicant's governance body for its current network.

- b. If, immediately prior to Designation, Applicant does not have a sufficient number of Participants or Subparticipants to meet the number of Participant or Subparticipant representative(s) indicated in response to Section 5.1(4)(f) of this SOP, then Applicant must submit a plan specifying how Applicant will comply with the requirements of Section 5.1(4)(f) within twelve (12) months following Designation and how it will fulfill the Governance Functions in the interim, which might include representation from entities that are likely to become Participants in Applicant's Designated Network. If Applicant does not meet such requirements within twelve (12) months following Designation, Applicant's Designation will be terminated.
- g) Applicant's Designated Network Governance Body must, at a minimum, approve the policies, and changes thereto, for the following aspects of Applicant's Designated Network (Governance Functions). Applicant's Designated Network Governance Body must also, at a minimum, participate in the process for each of the Governance Functions as described below. Nothing herein shall be deemed to limit the participation of Applicant's Designated Network Governance Body to only the minimum level of participation specified herein.
  - (i) **Technical framework.**
    - a. **Policy to be approved by Designated Network Governance Body:** Applicant must have a detailed policy that describes the oversight and control of the technical framework that enables the exchange of Required Information through its Designated Network (the Technical Framework Policy).
    - b. **Designated Network Governance Body Participation:** If the Designated Network Governance Body does not have final decision making authority with respect to decisions about the technical framework, then at a minimum, the Technical Framework Policy must include processes by which (1) the Designated Network Governance Body will receive reasonable prior notification of material changes to the technical framework; and (2) the Designated Network Governance Body can raise technical compliance issues or concerns to Applicant and the Designated Network Governance Body and Applicant will work together to reach an agreed upon resolution of such concerns to ensure

Applicant's compliance with Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE.

(ii) **Dispute resolution.**

- a. **Policy to be approved by the Designated Network Governance Body:** Applicant must have a detailed policy that describes how the following types of disputes will be resolved: (1) among Participants and Subparticipants in the Designated Network; and (2) between a Participant or Subparticipant and Applicant (the Dispute Resolution Policy). The Dispute Resolution Policy must also describe the Applicant's process for participating in the dispute resolution process mandated by the Common Agreement for any disputes between Applicant and another QHIN (e.g., who will participate in such process on behalf of Applicant).
- b. **Designated Network Governance Body Participation:** If the Designated Network Governance Body does not have decision-making authority to resolve disputes between Participants and Subparticipants in the Designated Network or between a Participant or Subparticipant and Applicant, the Dispute Resolution Policy must include processes by which the Designated Network Governance Body will be notified of the resolution of such disputes. The Dispute Resolution Policy must also include processes by which the Designated Network Governing Body will be notified of any disputes between Applicant and another QHIN and the resolution of such a dispute.

(iii) **Data breach response and management.**

- a. **Policy to be approved by the Designated Network Governance Body:** Applicant must have a detailed policy that describes how Applicant will respond to any potential or actual data breach involving Applicant's Designated Network (the Data Breach Response Policy).
- b. **Designated Network Governance Body Participation:** If the Designated Network Governance Body does not have decision-making authority to determine whether a data breach occurred in Applicant's Designated Network, then at a minimum, the Data Breach Response Policy must include processes by which the Designated Network Governance Body will be notified of any actual data breaches involving Applicant's Designated Network.

(iv) **Enforcement of Participant compliance with all applicable requirements for the Applicant's Designated Network.**

- a. **Policy to be approved by the Designated Network Governance Body:** Applicant must have a detailed policy that describes how sanctions will be imposed on any Designated Network Participant that violates the rules of Applicant’s Designated Network, including the suspension or termination of said Participant’s ability to use the Designated Network in the event of suspension or termination by the RCE (the Participant Enforcement Policy).
  - b. **Designated Network Governance Body Participation:** At a minimum, the Participant Enforcement Policy must include processes by which (1) the Designated Network Governance Body, or a subgroup thereof, will make any decisions regarding the suspension of a Participant or Subparticipant (except for any suspensions imposed by the RCE); (2) the Designated Network Governance Body will make any decisions regarding the termination of a Participant or Subparticipant (except for any terminations imposed by the RCE); and (3) the Designated Network Governance Body will be notified of any suspensions or terminations imposed by the RCE.
- (v) **Change management.**
  - a. **Policy to be approved by the Designated Network Governance Body:** Applicant must have a detailed policy for making changes to the Technical Framework Policy, Dispute Resolution Policy, Data Breach Response Policy, Participant Enforcement Policy, and Change Management Policy (the “Change Management Policy”).
  - b. **Designated Network Governance Body Participation:** At a minimum, the Change Management Policy must include processes by which the Designated Network Governance Body will make any final decisions regarding changes to the Technical Framework Policy, Dispute Resolution Policy, Data Breach Response Policy, Participant Enforcement Policy, and Change Management Policy.
- h) At the time of application, if Applicant uses a third-party technology vendor in connection with its Designated Network and such third-party vendor will have access to TEFCA Information, Applicant assures the third-party’s compliance with the Common Agreement and QTF, and all applicable SOPs, through a valid and enforceable written agreement that requires, at a minimum, that the third-party technology vendor: (1) comply with Applicable Law; (2) protect the privacy and security of any TEFCA Information (TI) to which the third-party technology vendor has access; (3) inform the Applicant of anything that meets the definition of a TEFCA Security Incident in the Common Agreement; and (4) reasonably cooperate with the Applicant on issues related to Applicant’s performance as a QHIN. If the agreement with the Applicant’s third-party technology vendor is not a Business Associate

Agreement, the agreement must require comparable levels of privacy and security protections that a Business Associate Agreement would provide. If the Applicant's Parent is providing the technology for the Designated Network, then Parent will be considered a third-party technology vendor for purposes of this requirement.

- i) At the time of application, Applicant must have the requisite financial and personnel resources to support its obligations as a QHIN. This includes but is not limited to the following:
  - (i) Applicant shall provide evidence of the organization's financial health to assure continuity of QHIN operations. This includes each of the following.
    - a. An attestation that Applicant is financially stable and has the fiscal resources to support operating as a QHIN without placing a financial strain on the rest of the organization; has available a minimum amount of cash, or cash equivalents, and borrowing arrangements (e.g., a line of credit) equal to six (6) months of operating reserves; and, has completed all mandatory filings with the Internal Revenue Service and Securities and Exchange Commission. This attestation must be provided at least at the time of application and again within thirty (30) calendar days prior to Designation.
    - b. \*If Applicant is relying upon its Parent's Historic Experience or is submitting its Parent's audited financials in response to Section 5.1(4)(i)(i)(c), then, in addition to the attestation required by Section 5.1(4)(i)(i)(a), Applicant must submit an attestation from Parent that Parent is financially stable and has the fiscal resources to support Applicant operating as a QHIN; has available a minimum amount of cash, or cash equivalents, and borrowing arrangements (e.g., a line of credit) equal to six (6) months of operating reserves; and, has completed all mandatory filings with the Internal Revenue Service and Securities and Exchange Commission. This attestation must be provided at least at the time of application and again within thirty (30) calendar days prior to Designation, and
    - c. \*The Applicant must have financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP) that have either been audited by an independent auditor or reviewed by an independent accountant. The Applicant must provide a copy of its most recent independent auditor's report or independent accountant's review report at the time of the application. Such report must have been signed by the auditor or accountant no more than twelve (12) months prior to the date of submission of Applicant's application. The independent auditor's report or independent accountant's review report must be based on financial statements

prepared in accordance with GAAP. Reports for financial statements prepared in accordance with another basis of accounting, such as cash basis, tax basis, modified accrual basis, or other specified basis of accounting, will not be accepted.

- i. If (1) the auditor’s opinion expresses substantial doubt about Applicant’s or Parent’s ability to continue as a going concern for a reasonable period of time<sup>4</sup> or identifies a material weakness<sup>5</sup> or (2) if the independent auditor’s report is based on a partial year of financials, Applicant must submit the independent auditor’s report for the subsequent full fiscal year prior to Designation. If the auditor’s opinion for the subsequent year of financials expresses substantial doubt about Applicant’s or Parent’s ability to continue as a going concern for a reasonable period of time or identifies a material weakness, then Applicant will not be Designated unless Applicant can demonstrate a material change in its financial circumstances since the audit was completed.
- ii. If (1) the independent accountant’s review report discloses a departure from GAAP, emphasis of a matter, or other explanatory information, or (2) if the independent accountant’s review report is based on a partial year of financials, Applicant must submit the independent accountant’s review report for the subsequent full fiscal year prior to Designation. If the independent accountant’s review report for the subsequent year of financials discloses a departure from GAAP, emphasis of a matter, or other explanatory information, then the applicant will be required to provide additional information to fully describe such matters. Applicant will not be Designated unless Applicant can demonstrate it has complied with GAAP and satisfactorily addressed the emphasis of a matter or other explanatory information in the report.

---

<sup>4</sup> For additional information about auditor’s considerations of an entity’s ability to continue as a going concern, see <https://pcaobus.org/oversight/standards/auditing-standards/details/AS2415>.

<sup>5</sup> A “material weakness” is “a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis.” See [https://pcaobus.org/oversight/standards/archived-standards/pre-reorganized-auditing-standards-interpretations/details/Auditing\\_Standard\\_5\\_Appendix\\_A#:~:text=A%20material%20weakness%20is%20a,detecte d%20on%20a%20timely%20basis](https://pcaobus.org/oversight/standards/archived-standards/pre-reorganized-auditing-standards-interpretations/details/Auditing_Standard_5_Appendix_A#:~:text=A%20material%20weakness%20is%20a,detecte d%20on%20a%20timely%20basis).

- (ii) Applicant shall describe the organizational structure and personnel who support the QHIN, including how these individuals work with the Designated Network Governance Body.
  - (iii) For each of general liability coverage and cyber risk/technology coverage including errors and omissions, Applicant shall provide evidence of one of the following: (1) a certificate of insurance demonstrating that Applicant has current insurance coverage as a primary or named insured sufficient to cover the maximum liability set forth in the Common Agreement and that meets the requirements set forth in an applicable SOP(s); (2) that Applicant has applied for such coverage, including a timeline in the project plan for obtaining such coverage and an attestation that Applicant will obtain the coverage prior to Applicant being Designated; or (3) available internal funds to cover the maximum liability. For the avoidance of doubt, the general liability coverage and the cyber risk/technology coverage should each have limits of at least \$2,000,000 per incident and \$5,000,000 in the aggregate. Such limits can be met through primary coverage, excess coverage, available internal funds, or a combination thereof. To the extent Applicant is relying on available internal funds for the required coverage amounts, such funds must be separate from those attested to in Section 5.1(4)(i)(i) of this SOP. Evidence provided in response to this section must be confirmed and updated as necessary, and at least no more than thirty (30) days prior to Designation.
- j) Applicant must have a formalized structure, resources, and controls to satisfy the privacy and security requirements of the Common Agreement and related SOPs, as well as evidence of compliance as specified in related SOPs.
- (i) Applicant must provide a letter of certification or certificate showing that it is certified under a nationally recognized security framework from a list of pre-approved certifications/certifying bodies developed by the RCE, as required by the QHIN Security Requirements for the Protection of TEFCA Information (TI) SOP, and the scope of the certification assessment. If Applicant does not have evidence of certification at the time of application, Applicant must provide documentation that certification will be achieved within twelve (12) months of application acceptance. Such evidence of certification must be current and provided prior to Designation. For the avoidance of doubt, an Applicant cannot be Designated without such certification. If Applicant fails to obtain certification within such twelve (12) month period, the Applicant will not be Designated and its application will be deemed denied. If the Applicant provides the RCE with factual and verifiable information that supports providing the Applicant with additional time to complete the certification

on the basis of relevant circumstances that render it impossible for the Applicant to obtain certification within the twelve (12) month timeframe through no fault of the Applicant, the RCE may agree to grant Applicant an extension of the initial twelve (12) month timeline at its sole discretion. The RCE is under no obligation to provide an Applicant with additional time beyond the initial twelve (12) months. The Applicant is responsible for keeping the RCE informed about any material developments that may delay the Applicant from receiving certification.

- (ii) From the time of application, Applicant must have a named person to serve as its Chief Information Security Officer (CISO) and for purposes of Applicant's participation in TEFCA exchange via a Framework Agreement attest that the CISO will have responsibility for monitoring and maintaining Applicant's overall security posture related to Applicant's participation in TEFCA Exchange. This includes technical, administrative, physical, and documentation security safeguards for Applicant's organization. This role may be subcontracted, but the CISO's overall responsibilities must encompass the spectrum of security related activities for the QHIN as an organizational entity, and not be limited to the activities of a third-party such as a platform vendor.
- (iii) For any Health Information Network operated by Applicant, at the time of application, Applicant must disclose whether there have been any Health Insurance Portability and Accountability Act (HIPAA) reportable breaches of ePHI over the past three (3) years, including the name of the Covered Entity and Business Associate(s) involved, the Covered Entity type, the breach submission date, the state, the number of individuals affected by the breach, the type of breach, and the location of breached information.<sup>6</sup> If Applicant is relying upon its Parent's Current Network to meet the Historic Experience requirement, then Applicant must provide the required information related to such Parent Organization.

k) Applicant participation in other Health Information Networks.

- (i) Suspension from other Health Information Networks. At the time of application and throughout the application, Onboarding, and Designation process, Applicant shall not be suspended, voluntarily or involuntarily, from participation in any other Health Information Network. In the event that Applicant is suspended from another Health Information Network, voluntarily or involuntarily, during the application, Onboarding, and Designation process, Applicant shall report such event to the RCE within two (2) business days of becoming aware of such suspension. All

---

<sup>6</sup> [https://ocrportal.hhs.gov/ocr/breach/breach\\_report.jsf](https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf)



application review, Onboarding, and Designation processes shall be suspended during the period that Applicant remains suspended from such other Health Information Network. In the event such suspension occurs following Designation, Applicant shall report such event to the RCE within one (1) business day and the RCE shall evaluate the circumstances on a case-by-case basis to determine whether they demonstrate that Applicant lacks the resources and infrastructure to support a reliable and trusted network or perform all of the required functions of a QHIN in the manner required by the Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE.

- (ii) Involuntary Termination from other Health Information Networks. At the time of application and throughout the application, Onboarding, and Designation process, Applicant shall not have been terminated from any other Health Information Network for cause in the twenty-four (24) months preceding submission of the application. In the event that Applicant is terminated from another Health Information Network for cause during the application, Onboarding, and Designation process, Applicant shall report such event to the RCE within two (2) business days of becoming aware of such termination and will be disqualified from Designation. In the event such termination occurs following Designation, Applicant shall report such event to the RCE within one (1) business day and the RCE shall evaluate the circumstances on a case-by-case basis to determine whether they demonstrate that Applicant lacks the resources and infrastructure to support a reliable and trusted network or perform all of the required functions of a QHIN in the manner required by the Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE.
- (iii) Voluntary Termination from other Health Information Networks. If Applicant has voluntarily terminated its participation in any other Health Information Network in the twenty-four (24) months preceding submission of the application, then Applicant shall disclose such voluntary termination and details regarding the applicable circumstances in its QHIN application. If Applicant voluntarily terminates its participation in any other Health Information Network during the application, Onboarding and Designation process or following Designation, then Applicant shall disclose such voluntary termination to the RCE within two (2) business days of such voluntary termination. The RCE shall evaluate the circumstances on a case-by-case basis to determine whether they demonstrate that Applicant or QHIN, as applicable, lacks the resources and infrastructure to support a reliable and trusted network or perform all of the required functions of a

QHIN in the manner required by the Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE.

- (iv) \*If Applicant is relying upon its Parent’s Current Network to meet the Historic Experience requirement, then Applicant must provide the information regarding suspensions or terminations related to such Parent’s Current Network.

## 5.2 QHIN Application Process

### a) Beginning the application process

The entity seeking to be Designated as a QHIN must inform the RCE of its intent to apply by submitting written communication to [QHINOnboarding@sequoiaproject.org](mailto:QHINOnboarding@sequoiaproject.org) with subject line “Intent to apply for QHIN Designation.” Written communication must include, in the body of the email: (1) legal name of Applicant organization as it will appear in the QHIN Application; (2) expected date of QHIN Application submission; (3) primary contact details for Applicant organization’s QHIN Application submission, including name, email address, phone number, and title/role within the organization; and (4) confirmation that the entity will comply with the RCE Communication Protocols, available at <https://rce.sequoiaproject.org/tefca-and-rce-resources/>.

Upon receipt of the intent to apply, the RCE will provide the entity with the Onboarding process documents to become a QHIN and schedule a virtual consultation with the entity to review the Eligibility Requirements and Onboarding process documents and answer any clarifying questions. The Onboarding process documents that the RCE provides to the entity shall include the following: (1) this QHIN Onboarding & Designation SOP, (2) a copy of the Common Agreement for signature, (3) QHIN Application, the form of which has been approved by ASTP, (4) Means to Demonstrate U.S. Ownership and Control of a QHIN SOP, and (5) Means to Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire.

The entity MUST submit the entirety of the QHIN Application within ninety (90) calendar days following RCE’s receipt of the intent to apply or the intent to apply will be deemed withdrawn. The QHIN Application is to be completed and submitted in its entirety to the RCE for review, along with a signed copy of the Common Agreement. Instructions for submission will be provided by the RCE.

Applicants must submit the completed Means to Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire along with the QHIN Application. Applicants are encouraged, but not required to submit the Means to Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire prior to submission of the completed application.

Applicants are encouraged, but not required, to successfully pass testing via the test platform outlined in Section 5.3 of this SOP prior to submitting their QHIN Application to mitigate the risk of delay in the Conformance Testing Process.

## **b) RCE review of applications for completeness**

Upon receipt of an application, the RCE will review the application to determine if the Applicant has responded to all questions and provided supporting documentation. If the application is not complete, the RCE will notify the Applicant within thirty (30) calendar days of receipt of the application what information is required to make the application complete. Once the RCE has determined that the application is complete, the RCE will notify the Applicant in writing that its application has been accepted for review. The acceptance of an application for review does not mean that the Applicant will be Designated as a QHIN; the Applicant must demonstrate that it meets all of the requirements to be Designated as a QHIN.

## **c) RCE review of complete applications**

Once the RCE determines that the application is complete, it will begin its review of the application to determine whether the Applicant meets the Eligibility Requirements to be Designated as a QHIN. The RCE will complete its review within sixty (60) calendar days of notifying the Applicant that its application is “complete.” The RCE may extend this period by providing notice to the Applicant.

The RCE may contact the Applicant with questions as the RCE reviews the application. The Applicant will have ten (10) business days to respond with answers to questions from the RCE, unless the RCE agrees to extend this period. It is important that the Applicant respond to the RCE promptly so that the RCE can complete its review within the desired timeframe. If the Applicant fails to respond to the RCE’s questions within ten (10) business days or such other time period as agreed upon by the RCE, then the application shall be deemed to have been withdrawn by the Applicant and the RCE will provide written notice to the Applicant that the application has been deemed withdrawn. The effect of this withdrawal is to end all review by the RCE. See Section 5.4 of this SOP for more information on withdrawals.

The application contains several different sections that require the Applicant to demonstrate its ability to comply with the different Eligibility Requirements. The RCE will have different sections of the application reviewed by different RCE team members depending upon each team member’s expertise. During the review of the application, if the RCE determines that the Applicant has failed to demonstrate that it satisfies any Eligibility Requirement or other requirement(s), the RCE will stop its review and deny the application.

If the RCE denies an application, it will notify the Applicant of the denial and will identify why the application was denied. Applicants should understand that there may be additional failures to comply that the RCE has not yet identified at the time that it identifies non-compliance and denies the application. Due to limited resources, the RCE is not in a position to continue to review an application once the RCE has determined that the application should be denied. If an application is denied, the Applicant has two options:

Re-application: If an application is denied, the Applicant can reapply no sooner than six (6) calendar months after the date shown on the notice of denial with a new application that includes all required information and that specifically addresses the deficiencies noted as the basis for denial of the Applicant’s previous application. The Applicant must make it very clear in its re-application how it has addressed the reason(s) for denial that the RCE listed in its notice of denial for the first application. The RCE will review a re-application solely on the basis of what is included in the re-application; the Applicant cannot rely upon information or documents that were previously submitted to the RCE.

Appeal of denial: An Applicant may appeal the RCE’s denial of its QHIN Application to the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP) of the U.S. Department of Health and Human Services. The *Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (HTI-2) Final Rule* addresses appeals of denied QHIN Applications. In the event an Applicant appeals the RCE’s denial of its QHIN Application, the RCE shall forward all of Applicant’s QHIN Application materials to ASTP within ten (10) business days of the RCE receiving notice of Applicant’s appeal.

### 5.3 Pre-Production Testing Process

#### a) QHIN Onboarding

Onboarding begins when an Applicant QHIN has signed the Common Agreement and received notice from the RCE that their QHIN Application meets all eligibility criteria and has been accepted for testing. Applicant QHIN will then be considered a Candidate QHIN.

#### b) QHIN Onboarding Process

During the Onboarding process, the Candidate QHIN will have regular check-ins with its RCE contact to discuss the progress on any outstanding requirements and project plan elements and coordinate technical testing.

#### c) Testing Overview

This section outlines the steps that Candidate QHINs must take to demonstrate that their Designated Network can connect to those of other QHINs.

The testing and connectivity validation approach outlined rely on QHINs serving as testing and validation partners for Candidate QHINs. All QHINs have an obligation to serve as testing and validation partners at the request of other QHINs or Candidate QHINs. QHINs and Candidate QHINs are strongly encouraged to coordinate with one another to distribute the effort of serving as testing and validation partners among the community of QHINs and Candidate QHINs.

As detailed below, Candidate QHINs will be required to complete:

- (i) Conformance Testing Process
- (ii) Non-Production Partner Testing
- (iii) Production Connectivity Validation
- (iv) Pre-Production Testing Timeline

A Candidate QHIN must successfully complete the Conformance Testing Process and the Non-Production Partner Testing (collectively, “Pre-Production Testing”) within twelve (12) calendar months of acceptance and referral of its application to testing by the RCE, unless that timeframe is extended in ASTP’s or the RCE’s sole discretion by up to twelve (12) months. The Candidate QHIN is responsible for keeping the RCE informed about any material developments that may delay the Candidate QHIN from completing testing.

A Candidate QHIN that fails to complete Pre-Production Testing within twelve (12) calendar months or within the timeframe of any extension granted by ASTP or the RCE will receive a written Designation determination from the RCE notifying the Candidate QHIN that it is **not** Designated as a QHIN and all Onboarding and Designation activities will cease. An Applicant that receives a determination that it has been denied Designation cannot file a new application to be Designated as a QHIN until six (6) calendar months after the date of the Designation determination. If a Candidate QHIN is denied on the basis of its failure to complete Pre-Production Testing within the required timeframe and decides to later re-apply, the Applicant must submit a new intent to apply and application. The new application must include clear evidence that it has addressed the reason(s) the Applicant was unable to successfully complete these testing phases as a Candidate QHIN in its previous application. The RCE will review a re-application solely on the basis of what is included in the re-application; the Applicant cannot rely upon information or documents that were previously submitted to the RCE.

- (v) Conformance Testing Process

This section describes the scope, approach, and testing process for verifying that a Candidate QHIN complies with the QTF requirements, which are defined in the QHIN Testing Process documents. The Conformance Testing Process is intended to be a largely automated process augmented by minimal manual review to verify conformance of a Candidate QHIN’s Connectivity Services. The process will leverage an automated testing environment known as The Sequoia Project Interoperability Testing Platform (“ITP”). The ITP environment automates the tests and enables Candidate QHINs and their vendors to conduct practice testing on a self-service basis, with real-time feedback regarding issues of non-conformance.

To begin the Conformance Testing Process, Candidate QHINs must submit a testing application package,<sup>7</sup> which includes specific configuration information required to onboard the system under test to the ITP and information related to users who need to have accounts provisioned to access the tooling. Testing is self-service and is facilitated by the Candidate QHIN. Once testing is completed, the RCE will complete any manual testing required to verify all test results and generate a final test report. Candidate QHINs that successfully complete the program and pass all testing will be eligible to continue the Onboarding process for the specific version of the system that was validated.

#### (vi) Non-Production Partner Testing

Prior to implementing production connectivity, each Candidate QHIN will complete a series of non-production tests against the test instances of other QHIN gateways (“Test Ecosystem”). The Test Ecosystem will include an RCE Stage Directory where QHINs and Candidate QHINs can interact to obtain and update test gateway information. Test Ecosystem gateways and transactions will be secured using valid, non-production RCE certificates, as outlined in the Technical Trust Requirements.

Candidate QHINs are responsible for achieving 100% transaction success in the Test Ecosystem with all other QHINs who have completed Production Connectivity Validation. The RCE will inform each Candidate QHIN prior to non-production testing which QHINs they are responsible for testing with. For each identified QHIN, testing will consist of successfully completing each of the required transactions with each other QHIN. Each testing partner must report completion of successful testing to the RCE.

Test partners must NOT report success until all transactions have been completed and data has been returned to the other party in that transaction. Specifically, for QHIN Query transactions, matching patients must be found, at least one document must be available, and one or more documents must be retrieved. Data should be coordinated among the test partners such that patient matching is successful. For QHIN Message Delivery, a successful acknowledgement must be received from the responding QHIN.

All QHINs must assist future Candidate QHINs with their testing by maintaining a suitable test environment as further described below.

QHINs are required to add an entry into the Test Ecosystem’s RCE Stage Directory that is available for testing at any time. QHINs are required to maintain their entry(ies) in this directory that reasonably represent their production environment. QHINs MAY add additional entries to the Test Ecosystem Directory if they so choose.

---

<sup>7</sup> Together with submitting the testing application package, the Candidate QHIN shall attest that they reasonably believe the system(s) used are compliant with the technical specifications outlined in the QTF.



Entries in the Test Ecosystem Directory, and the gateway(s) behind them, should behave substantially similarly to the production environment without access to production or ePHI data. Specifically, test partners should expect that the same query that yielded a successful test with entries in the Test Ecosystem Directory would yield a non-errored query response in production. These test entries must ONLY return information consisting of synthetic patient data, including demographics and retrievable files. **No production clinical data should be available via gateways published in the Test Ecosystem Directory.** QHINs MUST ensure that their test gateway is active and ready to reply to test queries. Failure to repair these test entries in a timely manner may result in punitive actions from the RCE which may include, but are not limited to, a denial of access to the Production RCE Directory Service.

## 5.4 Application Withdrawals

An Applicant may voluntarily withdraw its application at any point prior to Designation by providing written notice to the RCE via email to [QHINOnboarding@sequoiaproject.org](mailto:QHINOnboarding@sequoiaproject.org), subject “Applicant Withdrawal.” Should the Applicant wish to reapply, Applicant must resubmit an intent to apply and submit a new application that includes all required information. The RCE will review a re-application solely on the basis of what is included in the re-application; the Applicant cannot rely upon information or documents that were previously submitted to the RCE.

If an application is deemed withdrawn as a result of the Applicant’s failure to respond to requests for information, the Applicant can reapply no sooner than six (6) calendar months after the date on which its previous application was submitted. Should the Applicant wish to reapply, Applicant must resubmit an intent to apply, explain how they have addressed the reasoning for the previous withdrawal, and submit a new application that includes all required information. If the withdrawal was determined because of non-response to RCE questions during the application completeness review phase, the new application must include all required information and specifically address the question(s) to which the Applicant previously failed to respond and an explanation as to why no response was previously provided within the required timeframe. The RCE will review a re-application solely on the basis of what is included in the re-application; the Applicant cannot rely upon information or documents that were previously submitted to the RCE.

## 5.4 Designation & Post-Production Testing

### a) Designation

After successfully completing the non-production partner testing, the Candidate QHIN will (1) provide evidence that all requirements for Designation have been completed, satisfying all requirements of the QHIN Application process; and (2) attest that any necessary system changes to complete non-production partner testing have been moved into the Production environment.

The RCE will determine whether all requirements for Designation have been completed, satisfying all requirements of the QHIN Application process. If all requirements have been satisfied, the RCE will (1) countersign the Common Agreement and (2) provide the Candidate



QHIN with the RCE's written Designation determination indicating that the Candidate QHIN has been Designated by the RCE.

#### **b) Production Connectivity Validation**

A QHIN MUST obtain their production certificate from the Certificate Authority and publish their first entry in the Production RCE Directory Service within five (5) business days following the date they receive written Designation from the RCE.

Once the RCE has provided the QHIN with written Designation, the QHIN may configure its production system for connectivity. Until the validation process described in this section is successfully completed, other QHINs are not obligated to engage in TEFCA Exchange activities with the QHIN, other than those required for the connectivity validation as described in this section.

A QHIN must initiate a Patient Discovery transaction to all other QHINs and must receive a successful response for all of these transactions. Such a response is "successful" if it is received and processed without error by the initiating system.

While general experience shows that receiving the "No Matching Patient Found" response for a non-production test patient is a reasonable method for establishing that connectivity will likely be successful between two parties, it does not guarantee that there is not a configuration issue related to the other required transactions. Therefore, all QHINs must complete testing with a Production Validation Partner. A QHIN must coordinate data with its Production Validation Partner such that connectivity can be confirmed for all required transactions for that QHIN.

Validation with a Production Validation Partner may use data from an actual shared patient so long as any appropriate access policy requirements and Exchange Purpose requirements are met. If it is not possible to do so under policy constraints, coordinated non-production test patient data can be used.

Upon completion of the validation to the Production Validation Partner's satisfaction, the Production Validation Partner will independently inform the RCE that the QHIN's production partner validation was successfully completed.

Within thirty (30) calendar days of receiving its written Designation, each QHIN must demonstrate that it has completed a successful transaction with all other in-production QHINs.

If a QHIN is unable to complete Production Connectivity Validation within the thirty (30) calendar day period provided, the QHIN must provide to the RCE, no later than day thirty (30), a written explanation as to why the QHIN is unable to complete this validation process within the allotted time and include a detailed plan and timeline for completion of this validation process. ASTP (or, with ASTP's prior authorization, the RCE) will review and either approve or reject the QHIN's plan for completing Production Connectivity Validation based on the reasonableness of the

explanation and the specific facts and circumstances, within five (5) business days of receipt. If the plan is accepted, then within thirty (30) calendar days of the end of the term of the plan, each QHIN must demonstrate in a manner specified by ASTP (or, with ASTP's prior authorization, the RCE) that it has completed a successful transaction with all other in-production QHINs according to standards and procedures for TEFCA Exchange.

If the QHIN fails to provide its plan or the plan is rejected, ASTP (or, with ASTP's prior authorization, the RCE) will rescind its approval of the application and terminate the QHIN Designation. A QHIN that has its Designation terminated may appeal the termination per the Common Agreement.

A QHIN that has its Designation terminated for failure to timely complete Production Connectivity Validation may not reapply to be Designated as a QHIN until at least six (6) calendar months after the date of such termination. Should the previously Designated QHIN wish to reapply, it must resubmit an intent to apply, explain how it has addressed the reasoning for the previous termination, and submit a new application that includes all required information. The new application must include clear and compelling evidence that the Applicant has addressed the reason(s) it was unable to successfully complete this testing phase during the Applicant's prior Designation. The RCE will review a re-application solely on the basis of what is included in the re-application. The Applicant cannot rely upon information or documents that were previously submitted to the RCE.

## 5.6 Changes to the Application

If at any time during the application process or following Designation, any information submitted materially changes or becomes untrue, Applicant must notify the RCE of such changes in writing within five (5) business days. The RCE may contact the Applicant with questions or requests for further information or documentation of the material change. The Applicant will have ten (10) business days to respond with answers to questions or requests for information from the RCE, unless the RCE agrees to extend this period.

## 6. VERSION HISTORY

Version #	Revision Date	Section #(s) of Update
<b>1.0</b>	August 31, 2022	N/A
<b>1.1</b>	September 16, 2022	Part 4, Section I.4(a)
<b>1.2</b>	September 30, 2022	<ul style="list-style-type: none"> <li>• Part 4, Section I.4(a)(i)(i)</li> <li>• Part 4, Section I.4(a)(i)(iii)</li> <li>• Part 6</li> </ul>
<b>2.0</b>	January 25, 2023	<ul style="list-style-type: none"> <li>• Part 4, Section I</li> <li>• Part 4, Section II.3(c)</li> </ul>
<b>2.1</b>	October 2023	<ul style="list-style-type: none"> <li>• Part 1 and Part 3</li> <li>• Part 4, Section I, II, III, and IV</li> </ul>
<b>3.0</b>	January 2025	<ul style="list-style-type: none"> <li>• All sections</li> </ul>