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Standard Operating Procedure (SOP): QHIN Onboarding & Designation

Version 2.1 (updated as of November 3, 2023)

Applicability: RCE; Entities seeking to be Designated as a QHIN; QHINs in Production
Connectivity Validation testing

1 COMMON AGREEMENT REFERENCES AND DEFINITIONS

The Common Agreement, under Section 4, addresses the Designation of QHINs. Section 4.1 requires anyone seeking to be designated as a QHIN to demonstrate that it meets the QHIN Eligibility Criteria. Section 4.3 requires anyone seeking to be Designated as a QHIN to submit an application to the RCE that demonstrates how the Applicant meets the QHIN Eligibility Criteria.

Text quoted in bold below is from the Common Agreement. Capitalized terms used below without definitions shall have the respective meanings assigned to such terms in the Common Agreement, QHIN Technical Framework (QTF), and associated SOPs.

Applicant or Applicant QHIN: means any organization that has submitted an Intent to Apply to be a QHIN to the RCE as specified in Part 4, Section II of this SOP, and has not withdrawn that Intent to Apply. Applicant also includes those organizations that have submitted a QHIN Application to the RCE for completeness review as set forth in Part 4, Section II of this SOP.

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 Part 4, Section III of this SOP.

2 PURPOSE

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

3 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/>.

4 PROCEDURE

Section I: 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. For the purposes of this SOP, “Designated Network” means the Health Information Network that the Signatory uses to provide Connectivity Services. A Designated Network may be a standalone Health Information Network or part of a pre-existing Health Information Network.

Signatory 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 Signatory is a subsidiary of a Parent and Signatory does not itself meet the eligibility criteria, Signatory 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 Signatory does not provide information about itself and its current Health Information Network(s) nor its Parent and Parent’s Current Network, Signatory 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 Signatory must demonstrate that Signatory meets the requirement itself without reliance on Parent or Parent’s Current Network.

1. **Common Agreement Criterion: “Signatory must demonstrate that it meets the definition of a U.S. Entity and is not owned or controlled by any non-U.S. person(s) or entity(-ies). The specific, required means to demonstrate this are set forth in an SOP.”**
 - a. At the time of application, Signatory must provide a copy of its charter or equivalent document issued by the Secretary of State, or similar government agency, for the jurisdiction in which the Signatory is legally organized or incorporated. Signatory shall provide its principal place of business, which shall be within the United States.
 - b. At the time of application, Signatory must provide a certificate of good standing, or similar document, issued and certified by the relevant governmental authority for the jurisdiction in which Signatory is domiciled and dated within ninety (90) calendar days of the date of Signatory’s QHIN Application.
 - c. At the time of application, Signatory 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. Signatory must attest that the document submitted are current and complete.
 - d. At the time of application, Signatory must complete the Means to Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire. Prior to application approval, Signatory must not be disqualified pursuant to Section 4.1 of the Means to Demonstrate U.S. Ownership and Control of a QHIN SOP, and, if applicable, must

receive a determination that Signatory 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 able to exchange Required Information, as defined in this Common Agreement. The specific, required means to demonstrate this are set forth in an SOP.”

a. At the time of application, Signatory must meet directly, or indirectly through its Parent, the following:

- (i) *Signatory must describe the purposes for exchange that are currently permitted on its current network, which must include at least one of the Exchange Purposes or a substantially similar purpose;
- (ii) *Signatory must conduct the exchange of information between at least two unaffiliated organizations. Signatory must 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) *Signatory 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 Exchange Purposes; and (ii) initiating transactions for the Exchange Purposes that Signatory will permit its Participants and Subparticipants to send through its Designated Network. If Signatory is not capable of (i) or (ii) at the time of application, it must provide a project plan for doing so through its Designated Network prior to beginning the testing required in Part 4, Section III of this SOP.

3. Common Agreement Criterion: “Signatory must demonstrate that it has the ability to perform all of the 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. Signatory can demonstrate this by having been in operation and supporting the query functionality as outlined in the QTF, or other functionally comparable exchange method, for at least the twelve (12) calendar months immediately preceding its application to be Designated. However, the RCE will consider other evidence that Signatory may offer to demonstrate compliance with this eligibility criterion as more fully set forth in the applicable SOP. Notwithstanding the foregoing, if Signatory does not demonstrate that it has been supporting query functionality as outlined in the QTF, the RCE may deem this requirement to be satisfied on an interim basis and Designate Signatory under a provisional status, subject to additional monitoring as further provided in the Onboarding & Designation SOP, including additional review during a provisional period.”

It is anticipated that QHINs may process tens of millions of transactions¹ 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 Performance Network:

- (i) *At the time of application, Signatory must demonstrate that its current network performs at least one (1) million transactions per day.
- (ii) At the time of application, Signatory must provide specific information regarding its current network (or Parent's Current Network) architecture, and its Designated Network architecture. Signatory must provide details in the project plan on how its Designated Network 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 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, Signatory must provide specific evidence of its current network having been in operation and supporting (i) the query functionality, as outlined in the QHIN Technical Framework (QTF),² for at least the twelve (12) consecutive calendar months immediately preceding its application to be Designated as a QHIN ("the "QTF Experience"), or (ii) the transmission of Required Information using a different but functionally comparable exchange method³ 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 (the "Comparable Experience") (collectively, the "Historic Experience").
- (ii) At the time of application, Signatory 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 Signatory's current network (or Parent's Current Network).

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

² "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 such Table.

³ "[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.

c. Provisional Status:

- (i) If Signatory only has evidence of Comparable Experience because it has not been supporting the query functionality as outlined in the QTF for at least twelve (12) consecutive calendar months immediately preceding its application to be Designated as a QHIN but otherwise meets all requirements for Designation, then Signatory's Designation will be on a provisional basis ("Provisional Status").
 - (ii) If Signatory is relying on the operations of Parent's Current Network to meet the Historic Experience Requirement but otherwise meets all requirements for Designation, then Signatory's Designation will be on the basis of Provisional Status.
 - (iii) The Provisional Status is a twelve (12) calendar month period in which a QHIN has the opportunity to demonstrate the ability to perform all required functions of a QHIN in the manner required by the Common Agreement, QTF, and applicable SOPs.
 - (iv) The RCE may impose such limitations on Signatory during its Provisional Status as the RCE deems reasonably necessary to allow the RCE to monitor Signatory's performance. This may include, but is not limited to, requiring Signatory to provide information about the type and volume of exchange activity, any problems that Signatory or its Participants or Subparticipants experience with exchange activity, participation in meetings with the RCE to discuss Signatory's performance during the Provisional Status, and any other matters that the RCE determines to be necessary. The Provisional Status shall continue for a period of twelve (12) calendar months following the RCE Designating Signatory as a QHIN in Provisional Status; provided, however, that the RCE has the right to suspend (and toll) or terminate Signatory's Designation at any point if the RCE determines that Signatory is not in compliance with the requirements and obligations that are applicable to QHINs, as more fully set forth in the applicable SOP.
 - (v) A QHIN in Provisional Status is a Designated QHIN that is subject to additional monitoring by the RCE for purposes of assuring the RCE that the QHIN is fully meeting the requirements of being a QHIN. QHINs may not discriminate against any QHIN, including those in Provisional Status, and all QHINs must exchange with one another as required by the Common Agreement, the SOPs, and the QTF.
- d. At the time of application, Signatory 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 Signatory's Designated Network

will be able to fully comply with the QTF prior to beginning the testing required in Part 4, Section III of this SOP.

- e. Following approval of the application but prior to Designation, Signatory 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 must demonstrate that it has in place, at the time of its application to be Designated, the organizational infrastructure and legal authority to comply with the obligations of the Common Agreement and a functioning system to govern its Health Information Network. In addition, Signatory must demonstrate it 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."

- a. QHINs must have a representative and participatory group or groups that approve the 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 Part 4, Section I.4(g) of this SOP. The Designated Network Governance Body will be considered representative and participatory if it meets the requirements set forth in Part 4, Section I.4(f) of this SOP.
- b. *At the time of application, Signatory 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, Signatory must submit a detailed description of how the Governance Functions for its Designated Network set forth in Part 4, Section I.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 Part 4, Section I.4(f) of this SOP.
- d. At the time of application, the Signatory 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 Signatory's corporate governing body (e.g., board of directors), Signatory's documentation 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 Signatory'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. Signatory must provide the documentation described in this Part 4, Section I.4(e) (the "Operational Documentation"). Signatory must provide the Operational Documentation at the time of application if Signatory has such Operational Documentation. If Signatory does not have such Operational Documentation, then in its project plan, Signatory 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 between Signatory and a Participant in the Designated Network that Signatory uses to enforce the policy, technical, and legal requirements of its Designated Network with its Participants. If Signatory does not have a network legal agreement, the burden is on Signatory to demonstrate that it does have a legally enforceable approach.
 - (ii) Process by which Signatory evaluates organizations to decide that they have the necessary technical, legal, and operational capability to participate in Signatory'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. Signatory'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 Signatory's Participants and Subparticipants will participate in Signatory's Designated Network Governance Body. Such Participant and Subparticipant representatives must have voting power, must be able to constitute a quorum of the Designated Network Governance Body (the "Quorum Requirement"), and must represent the diversity of Participants and Subparticipants in the Signatory's Designated Network. 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 Signatory 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 Part 4, Section I.4(d) of this SOP, which establishes the Designated Network Governance Body, must include: (1) eligibility criteria for Participant and Subparticipant representatives, (2) the number (or range) of individuals that participate on the Designated Network Governance Body, (3) the number (or range) of Participant and Subparticipant representatives, and (4) if applicable, the relationship to the existing Signatory's governance body for its current network.

- (ii) A minimum frequency with which meetings of the Designated Network Governance Body are required to take place (e.g., monthly, quarterly, etc.).
 - (iii) If, immediately prior to Designation, Signatory does not have a sufficient number of Participants or Subparticipants to meet the number of Participant or Subparticipant representatives indicated in response to Part 4, Section I.4(f)(i)(3) of this SOP, then Signatory may submit a plan specifying how Signatory will comply with the requirements of Section I.4(f)(i) and I.4(f)(ii) within twelve (12) calendar 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 Signatory's Designated Network. If such plan is acceptable to the RCE and Signatory has otherwise met all other requirements set forth in this SOP, then Signatory may be Designated on a provisional governance basis ("Provisional Governance Status"). Signatory will be removed from Provisional Governance Status once it attests that it complies with the requirements of Section I.4(f)(i) and I.4(f)(ii). If Signatory does not meet such requirements within twelve (12) calendar months following Designation, Signatory's Designation will be terminated. The RCE may extend this time period if the QHIN provides the RCE with factual and verifiable information that supports providing the QHIN with additional time to meet the requirements of Section I.4(f)(i) and I.4(f)(ii) on the basis of relevant circumstances that render it impossible for the QHIN to meet the requirements within the twelve (12) calendar month timeframe through no fault of the QHIN, and the RCE agrees to grant QHIN an extension.
 - (iv) QHINs may not discriminate against any QHIN, including those in Provisional Governance Status, and all QHINs must exchange with one another as required by the Common Agreement, the SOPs, and the QTF.
- g. Signatory's Designated Network Governance Body must, at a minimum, approve the policies, and changes thereto, for the following aspects of Signatory's Designated

Network (“Governance Functions”). Signatory’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 Signatory’s Designated Network Governance Body to only the minimum level of participation specified herein. If Signatory is Designated on Provisional Governance Status, Signatory may obtain approval and participation through its interim mechanisms until the Designated Network Governance Body is established.

(i) Technical framework.

- a. **Policy to be approved by Designated Network Governance Body:** Signatory 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 Signatory and the Designated Network Governance Body and Signatory will work together to reach an agreed upon resolution of such concerns to ensure Signatory’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:** Signatory 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 Signatory (the “Dispute Resolution Policy”). The Dispute Resolution Policy must also describe the Signatory’s process for participating in the dispute resolution process mandated by the Common Agreement for any disputes between Signatory and another QHIN (e.g., who will participate in such process on behalf of Signatory).
- b. **Designated Network Governance Body Participation:** If the Designated Network Governance Body does not have decision making

authority to resolve disputes between a Participant and Subparticipants in the Designated Network or between a Participant or Subparticipant and Signatory, 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 Signatory and another QHIN and the resolution of such a dispute.

- (iii) Data breach response and management.
- (iv) **Policy to be approved by the Designated Network Governance Body:** Signatory must have a detailed policy that describes how Signatory will respond to any potential or actual data breach involving Signatory's Designated Network (the "Data Breach Response Policy").
- (v) **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 Signatory'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 Signatory's Designated Network.
- (vi) Enforcement of Participant compliance with all applicable requirements for the Signatory's Designated Network.
- (vii) **Policy to be approved by the Designated Network Governance Body:** Signatory must have a detailed policy that describes how sanctions will be imposed on any Designated Network Participant that violates the rules of Signatory'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").
- (viii) **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.
- (ix) Change management.

- (x) **Policy to be approved by the Designated Network Governance Body:** Signatory 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”).
 - (xi) **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 Signatory uses a third-party technology vendor in connection with its Designated Network and such third-party vendor will have access to TEFCA Information, Signatory assures the third party’s compliance with the Common Agreement and QTF 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 Signatory’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, Signatory 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) Signatory 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 Signatory 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) calendar 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 the time of application and again within thirty (30) calendar days prior to Designation.

- b. If Signatory is relying upon its Parent’s Historic Experience or is submitting its Parent’s audited financials in response to Part 4, Section I.4(i)(i)(c), then, in addition to the attestation required by Part 4, Section I.4(i)(i)(a), Signatory must submit an attestation from Parent that Parent is financially stable and has the fiscal resources to support Signatory 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) calendar 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 the time of application and again within thirty (30) calendar days prior to Designation, and
 - c. *A copy of its most recent independent auditor’s report, which must have been signed by the auditor no more than twelve (12) calendar months prior to the date of submission of Signatory’s application. Such independent auditor’s report must be provided at the time of application. If (1) the auditor’s opinion expresses substantial doubt about Signatory’s or Parent’s ability to continue as a going concern for a reasonable period of time⁴ or identifies a material weakness⁵ or (2) if the independent auditor’s report is based on a partial year of financials, Signatory 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 Signatory’s or Parent’s ability to continue as a going concern for a reasonable period of time or identifies a material weakness, then Signatory will not be Designated unless Signatory can demonstrate a material change in its financial circumstances since the audit was completed. For all applications submitted on or after January 1, 2023, the independent auditor’s report must be based on financials prepared in accordance with generally accepted accounting principles.
- (ii) Signatory shall describe the organizational structure and personnel who support the QHIN, including how these individuals work with the Designated Network Governance Body.

⁴ 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>.

⁵ 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,detected%20on%20a%20timely%20basis.

- (iii) For each of general liability coverage and cyber risk/technology coverage including errors and omissions, Signatory shall provide evidence of one of the following: (1) a certificate of insurance demonstrating that Signatory has current insurance coverage as a primary or named insured sufficient to cover the maximum liability set forth in Section 7.4 in the Common Agreement or that meets the requirements set forth in an applicable SOP; (2) that Signatory has applied for such coverage, including a timeline in the project plan for obtaining such coverage and an attestation that Signatory will obtain the coverage prior to Signatory being Designated; or (3) available internal funds. 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, which limits can be met through primary coverage, excess coverage, available internal funds or a combination thereof. To the extent Signatory is relying on available internal funds for the required coverage amounts, such funds must be separate from those attested to in Part 4, Section 1.4(i)(i) of this SOP. Evidence provided in response to this section must be confirmed and updated as necessary no more than thirty (30) days prior to Designation.
- j. Security. Signatory 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) Signatory 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 TI SOP, and the scope of the certification assessment. If Signatory does not have evidence of certification at the time of application, Signatory must provide documentation that certification will be achieved within twelve (12) calendar months of application acceptance. Such evidence of certification must be current and provided prior to Designation. If Applicant fails to obtain certification within such twelve (12) month period, the Applicant will not be Designated, unless 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) calendar month timeframe through no fault of the Applicant, AND the RCE agrees to grant Applicant an extension. The RCE is under no obligation to provide an Applicant with additional time beyond twelve (12) calendar months. The Applicant is responsible for keeping the RCE informed about any material developments that may delay the Applicant from receiving certification.

- (ii) At the time of application, Signatory must have a named person to serve as its Chief Information Security Officer (CISO) and for purposes of Signatory's participation in TEFCA exchange via a Framework Agreement attest that the CISO will have responsibility for monitoring and maintaining Signatory's overall security posture related to Signatory's participation in TEFCA exchange. This includes technical, administrative, physical, and documentation security safeguards for Signatory'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 Signatory, at the time of application, Signatory 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 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.⁶ If Signatory is relying upon its Parent's Current Network to meet the Historic Experience requirement, then Signatory must provide the required information related to such Parent Organization.

k. Signatory 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, Signatory shall not be suspended, voluntarily or involuntarily, from participation in any other Health Information Network. In the event that Signatory is suspended from another Health Information Network, voluntarily or involuntarily, during the application, Onboarding and Designation process, Signatory shall report such event to the RCE within two (2) business days of becoming aware of such suspension. All application review, Onboarding and Designation processes shall be suspended during the period that Signatory remains suspended from such other Health Information Network. In the event such suspension occurs following Designation, Signatory 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 Signatory 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

⁶ https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf

this 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, Signatory 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 Signatory is terminated from another Health Information Network for cause during the application, Onboarding and Designation process, Signatory 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, Signatory 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 Signatory 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 this Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE.
- (iii) Voluntary Termination from other Health Information Networks. If Signatory has voluntarily terminated its participation in any other Health Information Network in the twenty-four (24) months preceding submission of the application, then Signatory shall disclose such voluntary termination and details regarding the applicable circumstances in its QHIN application. If Signatory voluntarily terminates its participation in any other Health Information Network during the application, Onboarding and Designation process, then Signatory 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 Signatory 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 this Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE.
- (iv) *If Signatory is relying upon its Parent's Current Network to meet the Historic Experience requirement, then Signatory must provide the information regarding suspensions or terminations related to such Parent's Current Network.

Section II: QHIN Application Process

1. 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 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, (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 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 complete application.

Applicants are encouraged but not required to successfully pass testing via the test platform outlined in Part 4, Section III of this SOP prior to submitting their QHIN Application to mitigate the risk of delay in the Conformance Testing Process related to the system under test.

2. 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 documents. 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. The RCE may extend this period by providing notice to the Applicant. 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.

3. 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 Criteria 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 applicable timeframe. If the Applicant fails to respond with satisfactory answers 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 without any further action by the RCE. The effect of this withdrawal is to end all review by the RCE.

If an application is deemed to have been withdrawn, the Applicant can reapply no sooner than six (6) calendar months after the date on which its previous application was submitted with a new application that includes all required information and that specifically addresses 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.

The application contains several different sections that require the Applicant to demonstrate its ability to comply with the different Eligibility Criteria. 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 by the team members, if the RCE determines that the Applicant has failed to demonstrate that it satisfies any Eligibility Criterion or other requirement, 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 review an application once the RCE has determined that the application should be denied. If an application is denied, the Applicant has two options:

- a. Re-application: If an application is denied, the Applicant can reapply 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 reapplication 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.
- b. Appeal of denial: An Applicant may appeal the RCE's denial of its QHIN application to ONC. ONC anticipates publishing regulations to address appeals of denied QHIN applications. ONC anticipates issuing sub-regulatory guidance to address those appeals while formulating regulations. Until ONC's regulations governing those appeals are finalized and effective, the sub-regulatory guidance ONC issues shall be binding. 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 ONC within ten (10) days of the RCE receiving notice of Applicant's appeal.
- c. Material Changes: If, following submission of the application, any information submitted becomes untrue or materially changes, Applicant must notify the RCE of such changes in writing within five (5) business days.

Section III: Pre-Production Testing Process

1. QHIN Onboarding

Onboarding begins when an Applicant QHIN has signed the Common Agreement and received approval of their QHIN Application. Applicant QHIN will then be considered a Candidate QHIN.

2. QHIN Onboarding Process

During the Onboarding Process, the Candidate QHIN will have regular check-ins with its RCE contact to denote the progress on any outstanding requirements and coordination of technical testing.

3. Testing Overview

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

The testing and connectivity validation approach outlined in these sections relies 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 the RCE on behalf 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:

- a. Conformance Testing Process
- b. Non-Production Partner Testing
- c. Production Connectivity Validation

4. 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 approval of its application by the RCE. If the Candidate QHIN fails to do so, the Candidate QHIN will not be Designated, unless the Candidate QHIN provides the RCE with factual and verifiable information that supports providing the Candidate QHIN with additional time to complete the testing on the basis of relevant testing circumstances that render it impossible for the Candidate QHIN to complete testing within the twelve (12) calendar month timeframe through no fault of the Candidate QHIN, AND the RCE agrees to grant Candidate an extension. The RCE is under no obligation to provide a Candidate QHIN with additional time beyond twelve (12) calendar 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 the RCE will receive a written Designation determination from the RCE notifying the Candidate QHIN that it is **not** Designated as a QHIN. A Candidate QHIN that receives a determination that it has been denied Designation cannot file a new application to be Designated as a QHIN until twelve (12) 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 Candidate QHIN must submit with its new application clear evidence that it has addressed the reason(s) the Candidate QHIN was unable to successfully complete these testing phases following its previous application. The RCE will review a re-application solely on the basis of what is included in the re-application; the Candidate QHIN cannot rely upon information or documents that were previously submitted to the RCE.

5. 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 systems and technology used by Candidate QHINs. The process will leverage an automated testing environment known as the Sequoia Interoperability Testing Platform (“ITP”). The ITP environment automates the tests and enables Candidates and 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,⁷ which denotes specific configuration information required to onboard the system under test to the Sequoia 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. Systems 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.

6. 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 Directory instance with which 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.

Candidate QHINs are responsible for conducting partner tests with all other QHINs.

The non-production partner tests will consist of successfully completing each of the required transactions.

Test partners must NOT report success until each transaction has been completed and data 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.

Candidate QHINs are required to achieve 100% transaction success with all in-production QHINs participating in the Test Ecosystem. The RCE recognizes that for the initial group of QHIN Candidates, there will not be any in-production QHINs against which a Candidate QHIN can test. **For this initial group of Candidate QHINs only**, each Candidate QHIN is required to achieve 100%

⁷ Together with submitting the testing application package, the Candidate QHIN shall attest that they reasonably believe the system or systems used are compliant with the technical specifications outlined in the QTF.

transaction success with **at least** one other Candidate QHIN. After the initial group of QHINs are Designated by the RCE, these QHINs will be the in-production QHINs for purposes of the testing requirement of achieving 100% transaction success. Once a Candidate QHIN is Designated, it must assist future Candidate QHINs with their testing by maintaining a suitable test environment as further described below.

QHINs that have received an RCE Directory Read/Write API key are required to add an entry into the Non-Production Test Ecosystem Directory that is available for testing at any time. QHINs are required to maintain entries in this directory that reasonably represent their production environment. QHINs MAY add additional entries to the Test Ecosystem Directory beyond the minimal list if they so choose.

Entries in the Test Ecosystem Directory, and the gateway(s) behind them, should behave substantially similarly to the production environment without access to Production 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 RCE Directory read/write privileges.

Section IV: Designation & Post-Production Testing

1. 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 (Part 4, Section II of this SOP); 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 section of this SOP. 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.

2. Production Connectivity Validation

Once the RCE has provided the Candidate 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 exchange activities with the QHIN, other than those required for the connectivity validation as described in this Section.

QHINs must initiate a Patient Discovery transaction to all other QHINs and must successfully receive a “No Matching Patient Found” 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 as long as any appropriate access policy 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 having its entry in the RCE Directory, 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) day period provided, the QHIN must provide to the RCE, no later than day thirty (30), an 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. The RCE will review and approve or reject the QHIN’s plan for completing Production Connectivity Validation within five (5) business days of receipt.

A QHIN’s failure to complete Production Connectivity Validation within thirty (30) calendar days may result in the RCE imposing sanctions against the QHIN, including, but not limited to: identification of the QHIN as “Not in Good Standing”; suspension of the QHIN’s representation in any of the Deliberative Bodies (as defined in the SOP “Conflicts of Interest”), including suspension of any voting rights therein while the QHIN remains “Not in Good Standing”; suspension from use of the Connectivity Services; and/or termination of the Common Agreement, thereby terminating the QHIN’s Designation status. The RCE retains the right to determine, in its sole discretion, which sanctions to impose. A QHIN that has its Designation terminated under this Section may dispute such termination through the Dispute Resolution Process or appeal the termination to ONC but shall be suspended from all QHIN activities and identified as “Inactive” during the pendency of the Dispute Resolution Process or appeal.

A QHIN that has its Designation terminated for failure to complete Production Connectivity Validation within thirty (30) calendar days or within the period of an extension, if any, granted by the RCE may not reapply to be Designated as a QHIN until at least twelve (12) calendar months after the date of such termination. 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. VERSION HISTORY

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