Standard Operating Procedure (SOP): QHIN Onboarding & Designation

Version 1.1 (updated as of September 16, 2022)

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

1 Common Agreement References

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.

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.

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 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. These documents must be attested to by the Secretary of the organization or another officer of the organization if there is no Secretary.

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). The determination regarding Foreign Control is not appealable.

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 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 the exchange of Required Information for all Exchange Purposes, as detailed in the Exchange Purposes SOP. If Signatory is not supporting the exchange of Required Information as detailed in the Exchange Purposes SOP 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 transactions[1] 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 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: At the time of application, Signatory must provide (i) specific evidence of its current network having been in operation and supporting the query functionality, as outlined in the QHIN Technical

[1] Current network transactions include transactions that are between the applicant and external entities, including between applicant and its participants within its current network.

Framework (QTF)[2] for at least the twelve (12) calendar months immediately preceding its application to be Designated as a QHIN, and (ii) a description of how that experience and resources will be leveraged in connection with the Designated Network if it is different from the Signatory's current network.

c. Provisional Status:

(i) If Signatory has not been supporting the query functionality as outlined in the QTF for at least twelve (12) calendar months immediately preceding its application to be Designated as a QHIN but can demonstrate that it has been engaged in the transmission of Required Information using a different but functionally comparable exchange method[3] 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, then Signatory may be Designated on a provisional basis provided Signatory satisfies all other requirements ("Provisional Status"). 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.

(ii) 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.

(iii) 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

[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.

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 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 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 perform the 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 it will perform the Governance Functions for its Designated Network set forth in Part 4, Section I.4(g) of this SOP. This must include a description of the Designated Network Governance Body, how the Governance Functions will be performed, the legal authority supporting the performance of the Governance Functions by the Designated Network Governance Body, 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 been granted the authority to perform the Governance Functions for the Designated Network. For example, if the Signatory's corporate organizational documents require the Signatory's corporate board of directors to delegate authority to the Designated Network Governance Body, the board resolution documenting such delegation must be provided.

e. At the time of application, the Signatory must provide all other documentation related to the implementation and operationalization of the Designated Network Governance Body and Governance Functions, to the extent Signatory has such documentation. If Signatory does not have such documentation, then in its project plan, Signatory must explain the steps it is taking to create such documentation for implementation and operationalization of the Designated Network Governance Body and Governance Functions and the timelines for doing so within twelve (12) calendar months of application acceptance. Such documentation must be provided prior to Designation. Documentation must describe or demonstrate the following:

   (i) How Signatory communicates the rules of Designated Network governance to participants in Signatory's Designated Network and legally obligates those participants to comply (e.g., contract terms, policies, or some other written form).

   (ii) Mechanisms for enforcing Designated Network requirements, including for onboarding entities to the Designated Network. Signatory must describe how Signatory evaluates organizations to decide that they have the necessary technical, legal, and operational capability to participate in Signatory's Designated Network.

   (iii) The legal means 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.

   (iv) 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.

   (v) How the Designated Network Governance Body will perform the Governance Functions.

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, and must represent the diversity of Participants and Subparticipants in the Signatory's Designated Network. 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 of 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 of 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 have responsibility, oversight, and control, including final decision-making authority, for the following aspects of Signatory's Designated Network ("Governance Functions"):

(i) **Technical framework**. Signatory must submit a detailed description of how the Governance Body oversees and controls the technical framework that enables the exchange of Required Information through its Designated Network.

(ii) **Resolution of disputes regarding use of Signatory's Designated Network.** Signatory shall provide a detailed description of such dispute resolution process and: (1) all disputes that have been processed through the dispute resolution process during the twenty-four (24) calendar months immediately preceding the submission of Signatory's application; (2) any disputes that are pending at the time Signatory submits its application; and (3) any legal claims filed during the twenty-four (24) calendar months immediately preceding the submission of Signatory's application that arose out of a dispute that was first brought to Signatory's dispute resolution process or that was permitted to bypass such process (e.g., a petition for injunctive relief), to the extent Signatory knows of any such legal claims. Signatory must provide the information for (1) – (3) for any Health Information Network operated by Signatory.

(iii) **Data breach response and management.** Signatory shall provide a detailed description of its response procedures for any data breach involving Signatory's Designated Network.

(iv) **Enforcement of Participant compliance with all applicable requirements for the Signatory's Designated Network.** Signatory shall provide a detailed description of its formalized process to impose sanctions 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.

(v) **Change management to implement changes to any of the above.** Signatory shall provide a detailed description of its change management procedure, including final approval from the Designated Network Governance Body.

h. At the time of application, if Signatory uses a third-party technology vendor for its Designated Network, explain how Signatory plans to conduct oversight of the third party and how Signatory will assure the third party's compliance with the Common Agreement and QTF, including 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.

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 an attestation of the organization's financial health to assure continuity of QHIN operations. This includes an attestation that Signatory 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, as well as copies of its audited financials for the prior two (2) years.

(ii) Signatory 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, errors and omissions, cyber risk/technology errors and omissions, and directors and officers, Signatory shall provide evidence of one of the following: (1) a certificate of insurance demonstrating that Signatory has current insurance coverage 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 an attestation that Signatory will obtain the coverage prior to Signatory being Designated; or (3) available internal funds, separate from those attested to in Part 4, Section I.4(i)(i) of this SOP, to self-insure in such amounts.

j. Security

(i) Signatory must provide evidence that it has been 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. 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 certification must be 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. Neither the applicant's non-Designation for failure to obtain certification within twelve (12) calendar months nor the RCE's denial of a request for an extension are appealable. 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 Chief Information Security Officer (CISO) and provide evidence that the CISO has executive-level responsibility for overseeing the security of Signatory's Designated Network.

(iii) For any Health Information Network operated by Signatory, at the time of application, Signatory must provide detailed information about any Health Insurance Portability and Accountability Act (HIPAA)-reportable breaches of ePHI over the past three (3) years, including the nature of the breach, the number of individuals affected by the breach, the remediation measures undertaken by Signatory, and the amount of any fines or penalties.

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 denial of its application only for one or more of the following reasons:

(i) The reason(s) for denial identified by the RCE is/are objectively incorrect due to an inadvertent error(s) by the RCE;

(ii) The RCE failed to follow the procedures set forth in this SOP, and this failure materially interfered with the applicant's ability to demonstrate that the applicant does satisfy the Eligibility Criteria. This would include, by way of example only, if the RCE failed to provide applicant with ten (10) business days to respond to questions from the RCE;

(iii) There is reasonable evidence that the RCE has not applied the Eligibility Criteria in a consistent manner across all applicants;

(iv) There is evidence that the RCE discriminated against the applicant in the RCE's review of the application;

(v) The RCE based its denial on something other than the Eligibility Criteria or other requirements imposed on QHINs by the Common Agreement, SOPs, or the QTF.

If an applicant wishes to appeal the denial of its application, the applicant must file with the RCE a written appeal within fifteen (15) business days of the date shown on the notice of denial. The appeal must set forth which of the five grounds for appeal the applicant is asserting and the evidence or information that the applicant is relying upon to support these grounds. The appeal must be signed by an executive, officer, or director of the applicant who has the express authority to legally bind the applicant. The RCE will review the appeal and prepare a summary of the appeal allegations within fifteen (15) business days of receiving the appeal from the applicant.

If the appeal occurs prior to the formation of the Transitional Council or the Governing Council, then this paragraph shall not apply. If the appeal occurs after the formation of the Transitional Council or the Governing Council, then the RCE will brief the Governing Council or the Transitional Council by providing it with a copy of the summary of the appeal. This summary will be labeled as confidential and shall not be further disclosed by any member of the Governing Council or the Transitional Council unless specifically directed to do so by the RCE. The RCE will seek input from the Governing Council or the Transitional Council about the merits of the appeal. The RCE will determine what input to seek and how best to obtain this input, but neither the Governing Council nor the Transitional Council will vote on the merits of any appeal.

Regardless of when the appeal occurs, the RCE may inform the Office of the National Coordinator for Health Information Technology (ONC) that an appeal has been filed and share the summary with ONC on a confidential basis. The RCE will consider any input that ONC provides on the merits of the appeal, but the decision on any appeal will be made by the RCE.

The RCE will make a decision on the appeal within seventy (70) calendar days of the appeal being filed with the RCE. The RCE may extend this period by providing notice to the applicant. The RCE can deny the appeal or grant the appeal. The decision of the RCE is final, subject to Signatory's right to escalate certain Disputes to ONC, as set forth in Section 15.6.1 of the Common Agreement, and the ONC's right to review the RCE's conduct, as set forth in Section 3.1 of the Common Agreement. If the RCE denies the appeal, the applicant cannot file a new application to be Designated as a QHIN until six (6) calendar months after the date of the denial of the appeal unless, subject to Section 15.6.1 or Section 3.1 of the Common Agreement, ONC specifies a shorter timeframe. Any new application must address how the applicant has addressed the reason(s) that its application was previously denied. If the RCE grants the appeal, then the RCE and applicant shall resume the Onboarding process as set forth in this SOP.

Section III: Pre-Production Testing Process

1. QHIN Onboarding

Onboarding begins when a prospective QHIN has signed the Common Agreement and received approval of their QHIN Application.

2. QHIN Onboarding Process

During the Onboarding Process, the applicant 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 prospective 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 prospective 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 applicants. QHINs and applicants 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 applicants.

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

a. Conformance Testing Process

b. Non-Production Partner Testing

c. Production Connectivity Validation

4. Pre-Production Testing Timeline

An applicant 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 applicant fails to do so, 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 testing on the basis of relevant testing circumstances that render it impossible for the applicant to complete testing 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. Neither the applicant's non-Designation for failure to complete Pre-Production Testing within twelve (12) calendar months nor the RCE's denial of a request for an extension are appealable. The applicant is responsible for keeping the RCE informed about any material developments that may delay the applicant from completing testing.

An applicant 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 applicant that it is **not** Designated as a QHIN. An applicant 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 an applicant 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 with its new application clear evidence that it has addressed the reason(s) the applicant 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 applicant 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 an applicant 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 applicants. The process will leverage an automated testing environment known as the Sequoia Interoperability Testing Platform ("ITP"). The ITP environment automates the tests and enables applicants 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, applicants must submit a testing application package[4], 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 applicant. 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 prospective 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 prospective QHINs can interact to obtain and update test gateway information. Test Ecosystem gateways and transactions will be secured using valid, non-production RCE certificates.

Prospective 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.

Prospective 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 applicants, there will not be any in-production QHINs against which an applicant can test. **For this initial group of applicants only,** each applicant is required to achieve 100% transaction success with **at least** one other QHIN applicant. 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 an applicant is Designated, it must assist future QHIN applicants with their testing by maintaining a suitable test environment as further described below.

[4] Together with submitting the testing application package, the applicant shall attest that they reasonably believe the system or systems used are compliant with the technical specifications outlined in the QTF.

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

2. Production Connectivity Validation

Once the RCE has provided applicant 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. The RCE's imposition of any sanctions under this Section, *other than* termination, is final and not appealable. A QHIN that has its Designation terminated under this Section may dispute such termination through the Dispute Resolution Process but shall be suspended from all QHIN activities and identified as "Inactive" during the pendency of the Dispute Resolution Process.

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. An applicant that has previously had its Designation terminated for failure to complete Production Connectivity Validation does **not** have the right to appeal a denial of its re-application.

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