



ONC  
TEFCA  
RECOGNIZED  
COORDINATING  
ENTITY

# Standard Operating Procedure (SOP): ONC Access to and Requests for Confidential Information

Applicability: Entities Seeking to be Designated as a  
QHIN, QHINs, Participants and Subparticipants, RCE

## 1 COMMON AGREEMENT REFERENCES

Capitalized terms used below without definitions shall have the respective meanings assigned to such terms in the Common Agreement in place at the time of posting of this SOP.

**CA Section 1.1:** Definitions:

- Confidential Information
- TEFCA Security Incident
- Threat Condition

**CA Section 6.1:** Cooperation.

**CA Section 7.1:** Confidential Information.

**CA Section 7.2:** Disclosure of Confidential Information.

**CA Section 7.3:** ONC's and the RCE's Approach when Requesting Confidential Information.

**CA Section 14.1:** Transparency – Access to Participant-QHIN Information.

## 2 PURPOSE

Section 7 of the Common Agreement addresses the use and disclosure of Confidential Information as well as ONC's and RCE's approach when requesting Confidential Information.

Included in the definition of Confidential Information is any confidential or proprietary materials that are marked as such and provided to the RCE by Designated QHINs, entities seeking to be Designated as QHINs, entities in the application process (from the submission of a letter of intent through the Designation of a QHIN), or Participants or Subparticipants to the extent such materials are in the RCE's possession when requested pursuant to this SOP (specifically referred to herein as "QHIN Confidential and Proprietary Materials"). This SOP sets forth the process for enabling ONC to request and access such QHIN Confidential and Proprietary Materials that are in the RCE's possession.

Process and materials related to evaluation of compliance with Section 4.1(i) of the Common Agreement is addressed by the Means to Demonstrate U.S. Ownership and Control of a Qualified Health Information Network SOP.



### 3 PROCEDURE

1. ONC Request and Access to QHIN Confidential and Proprietary Materials in the RCE's possession from entities that are in the application process (Applicant QHINs)
  - a. Upon written request from ONC, the RCE shall share QHIN Confidential and Proprietary Materials in the RCE's possession if ONC's request relates to a Threat Condition, as defined in the Common Agreement; or is necessary to inform, investigate, or address an event that could pose a risk to the interests of national security as directed by an agency of the United States government. The RCE shall notify the affected Applicant QHIN that ONC has requested access to QHIN Confidential and Proprietary Materials within three (3) business days after receiving ONC's request, unless ONC prohibits the RCE from making such communication.
    - i. The notification shall include:
      1. A list of the specific materials and information requested by ONC; and
      2. The purpose(s) for which ONC has requested the information.
  - b. If ONC requests access to QHIN Confidential and Proprietary Materials in the RCE's possession for reasons **other than those set forth in Section 1(a)**, the RCE shall notify the affected Applicant QHIN that ONC has requested access to QHIN Confidential and Proprietary Materials within five (5) business days after receiving ONC's request.
    - i. The notification shall include:
      1. A list of the specific materials and information requested by ONC; and
      2. The purpose(s) for which ONC has requested the information.
    - ii. Upon receipt of written notification from the RCE, the Applicant QHIN shall have five (5) business days to provide the RCE with written notice that contains the following elements: 1) acknowledging the request, and, if applicable, 2) stating any objections to sharing the requested QHIN Confidential and Proprietary Materials. Within five (5) business days after RCE's receipt of Applicant QHIN's response, the RCE shall notify ONC of the Applicant QHIN's objections, if any.



- iii. If the RCE does not receive a response from the Applicant QHIN within the time period set forth in Section 1(b)(ii), or if the Applicant QHIN informs the RCE that it has no objection, the requested information shall be shared with ONC within five (5) business days.
  - c. If the Applicant QHIN objects to the RCE providing ONC the requested QHIN Confidential and Proprietary Materials in accordance with Section 1(b)(ii), it shall have five (5) business days, or such longer period as may be agreed to by the RCE, after notifying the RCE of its objection to withdraw its QHIN application in compliance with any applicable processes set forth in the Onboarding and Designation SOP, in which case the requested QHIN Confidential and Proprietary Materials will not be disclosed to ONC.
  - d. The process set forth in this Section 1 is without prejudice to the RCE's suspension or termination rights set forth in the Onboarding and Designation SOP, applicable SOP(s), or the Common Agreement. The processes set forth in this SOP are specific to ONC's request for QHIN Confidential and Proprietary Materials that are in the RCE's possession.
2. ONC Request and Access to Confidential Information in the RCE's possession from Designated QHINs (or their Participants or Subparticipants)
- a. Upon written request from ONC, the RCE shall share QHIN Confidential and Proprietary Materials in the RCE's possession if ONC's request relates to:
    - i. A Threat Condition, as defined in the Common Agreement;
    - ii. Informing, investigating, or addressing an event that could pose a risk to the interests of national security as directed by an agency of the United States government;
    - iii. Informing, investigating, or addressing a TEFCA Security Incident; or
    - iv. Informing, investigating, or addressing an event that RCE or ONC believes will disrupt TEFCA exchange of TEFCA Information either due to the actual compromise of, or the need to mitigate, demonstrated vulnerabilities in systems of data of a QHIN, Participant, or Subparticipant, as applicable, or could be replicated in the systems, networks, applications, or data of another QHIN, Participant, or Subparticipant.
  - b. The written request from ONC set forth in Section 2(a) shall identify the reason(s) for the request. The RCE shall notify the affected QHIN that ONC has requested access to QHIN Confidential and Proprietary Materials within three (3) business



- days after receiving ONC's request unless ONC prohibits the RCE from making such communication.
- i. The RCE's notification shall include:
    1. A list of the specific materials and information requested by ONC; and
    2. The purpose(s) for which ONC has requested the information.
  - c. If ONC requests access to QHIN Confidential and Proprietary Materials in the RCE's possession for reasons **other than those set forth in Section 2(a)**, the RCE shall notify the QHIN that ONC has requested access to QHIN Confidential and Proprietary Materials within five (5) business days after receiving ONC's request.
    - i. The RCE's notification shall include:
      1. A list of the specific materials and information requested; and
      2. The purpose for which ONC requested the information.
    - ii. Upon receipt of written notification from the RCE the QHIN shall have five (5) business days to provide the RCE written notice that contains the following elements: 1) acknowledging the request, and 2) stating any objections to sharing the requested QHIN Confidential and Proprietary Materials. Should the information requested contain QHIN Participant or Subparticipant Confidential or Proprietary Materials, the QHIN is responsible for notifying the relevant Participant(s) or Subparticipant(s) of ONC's request. In this case, the QHIN shall have ten (10) business days to provide the RCE written notice containing the elements above. Within five (5) business days after RCE's receipt of the QHIN's response, RCE shall notify ONC of the QHIN's objections, if any.
    - iii. If the RCE does not receive a response from the QHIN within the time period set forth in Section 2(c)(ii), or if the QHIN informs RCE that they have no objection, the information shall be shared with ONC.
  - d. If the QHIN objects to the RCE providing ONC the requested QHIN Confidential and Proprietary Materials in accordance with Section 2(c)(ii), the RCE, ONC, and the QHIN shall work together in good faith to develop a compromise on the production of QHIN Confidential and Proprietary Materials. If the RCE, ONC, and the QHIN cannot develop such compromise within fifteen (15) business days after the RCE communicating the QHIN's initial objections to ONC or such longer period as the parties may agree, then the QHIN must either withdraw its objections or



give notice that it is terminating its participation in TEFCA. If the QHIN gives notice that it is terminating its participation in TEFCA, then the requested QHIN Confidential and Proprietary Materials will not be disclosed to ONC and the QHIN must effectuate such termination within a time period as may be agreed to by ONC and the RCE.

- e. The process set forth in this Section 2 is without prejudice to the RCE's suspension or termination rights set forth in the Common Agreement, Section 16 or Signatory's obligations and rights set forth in Sections 6.1 and 14.1 of the Common Agreement. The processes set forth in this SOP are specific to ONC's request for QHIN Confidential and Proprietary Materials that are in the RCE's possession. ONC and RCE reserve the right to request information and Signatory shall make available, upon written request, for the situations set forth in Section 14.1.

