

DRAFT: Standard Operating Procedure (SOP): Inquiries and Investigations

Version 1.0

Effective Date: __, 2026

Applicability: QHINs

1. COMMON AGREEMENT REFERENCES

The requirements set forth in this Standard Operating Procedure (SOP) are for implementation, in addition to the terms and conditions found in the applicable Framework Agreement, the Qualified Health Information Network® (QHIN™) Technical Framework (QTF), and applicable SOPs. The Trusted Exchange Framework and Common Agreement™ (TEFCA™) Cross Reference Resource identifies which SOPs provide additional detail on specific references from the Common Agreement.

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

2. DEFINITIONS

Select terms used throughout this SOP are defined in this Section for ease of reference. All capitalized terms used in this SOP have the respective meanings assigned to such term in the TEFCA Glossary.

Complainant: A QHIN, Participant, Subparticipant, or other third party that submits to the RCE a complaint about a QHIN or its Participants or Subparticipants.

Inquiry(ies): Question(s) that a QHIN has about another QHIN's, or another QHIN's Participant's or Subparticipant's, participation in TEFCA Exchange or compliance with the applicable Framework Agreements, SOPs, or QTF.

Investigated QHIN: A QHIN that is being investigated by the RCE for potential non-compliance with the Common Agreement, the SOPs, and the QTF.

Potential Non-Compliance Matter: An issue, matter, or complaint involving a QHIN, or its Participants or Subparticipants, in which the QHIN's compliance with the Common Agreement, SOPs, or QTF is in question.

3. PURPOSE

QHINs are required to comply with the Common Agreement, the SOPs, and the QTF. This SOP describes the process that QHINs must use to escalate questions about another QHIN's compliance with the Common Agreement, the SOPs, and the QTF and provides the process that the RCE will use to investigate matters of potential non-compliance.

4. PROCEDURE

4.1 RCE's Investigation of Potential Non-Compliance Matters

1. A Potential Non-Compliance Matter may be identified through a variety of mechanisms including, but not limited to, issues identified by the RCE through operation of TEFCA (e.g., delayed reporting, Directory errors); good faith complaints about a QHIN or its Participants or Subparticipants submitted to the RCE in writing in the form and format prescribed by the RCE by a Complainant that is requesting that the RCE undertake an investigation of the complaint or impose consequences on the QHIN; or, issues identified by a TEFCA Governance Body that the respective Governance Body has asked the RCE to investigate.
2. Once the RCE becomes aware of a Potential Non-Compliance Matter, the RCE will commence an investigation.
 - a. Within five (5) business days after becoming aware of a Potential Non-Compliance Matter, the RCE will notify the Investigated QHIN in writing that the RCE is commencing an investigation. The notification will include a summary of the Potential Non-Compliance Matter and, if applicable, the identity of the Complainant. The Complainant, if any, will not be copied on the notification.
 - b. Within five (5) business days after the RCE provides the Investigated QHIN with notice of the investigation, the RCE will hold an initial investigative meeting with the Investigated QHIN to gather context and background information about any Potential Non-Compliance Matter, unless the RCE and Investigated QHIN determine that such meeting is not necessary. The Complainant, if any, will not be included in the investigative meeting. The RCE, in its discretion, may hold additional investigative meetings with the Investigated QHIN.
 - c. If a Complainant made the RCE aware of the Potential Non-Compliance Matter, then the RCE, in its discretion, may facilitate a meeting(s) between the Complainant and the Investigated QHIN to discuss the issue. The Complainant is encouraged, but not required, to participate in such meeting. For clarity, the RCE is not required to facilitate such a meeting, disclose information about its investigations or the findings thereof to the Complainant, nor disclose any of the Investigated QHIN's Confidential Information to the Complainant. Upon request from the Complainant, the RCE may inform the Complainant whether the investigation is ongoing or completed, but will not provide any substantive updates. **If the Complainant seeks to actively participate in the investigation and resolution process and the Complainant is a QHIN, Participant, or Subparticipant, then it would need to do so through the Dispute Resolution Process.**

- d. The RCE may request reasonable information be submitted by the Investigated QHIN or Complainant at any time. Information requests must be reasonable, proportionate, and relevant to the potential non-compliant behavior. The Investigated QHIN or a QHIN, Participant, or Subparticipant that is a Complainant may object to an information request if it believes it is overly broad or burdensome, responsive information is privileged, or responsive information is a trade secret. In any such objection, the Investigated QHIN or Complainant must state whether it is refusing to provide any information, why it is refusing to provide the information, and whether there is information it is willing to provide as an alternative to the requested information. Provided an information request meets these criteria, the Investigated QHIN or Complainant shall cooperate with such requests in accordance with the applicable Framework Agreement. The RCE, however, shall not have the authority to compel a response or the production of testimony or documents by the Investigated QHIN or Complainant as part of the investigation process. The Investigated QHIN shall have the ability to mark documents as containing “Confidential Information,” provided such information aligns with the definition of “Confidential Information” in the Common Agreement. Notwithstanding a “Confidential Information” designation, the RCE may share such information with the Governing Council and ONC as provided in this SOP. Absent a good faith objection to the RCE’s request for information, the Investigated QHIN’s or Complainant’s refusal to provide any requested information may be considered by the RCE in its determination of non-compliance and may result in a finding of non-compliance in and of itself.
3. At the conclusion of its investigation, the RCE will issue one of the following findings:
 - a. the RCE has obtained sufficient evidence that the Investigated QHIN complied with its obligations under the Common Agreement, SOPs, or QTF;
 - b. the RCE has obtained sufficient evidence that the Investigated QHIN failed to comply with its obligations under the Common Agreement, SOPs, or QTF, which may include the Investigated QHIN’s failure to ensure that its Participants or Subparticipants comply with their obligations under the ToP, SOPs, or QTF; or
 - c. the RCE is unable to make a determination as to whether the Investigated QHIN complied or failed to comply with its obligations under the Common Agreement, SOPs, or QTF because (i) the obligations are subject to interpretation and no definitive interpretation has previously been provided; or (ii) there is not sufficient evidence for the RCE to make a determination.

4. The RCE will document in an investigation report (i) a summary of the Potential Non-Compliance Matter; (ii) the steps taken by the RCE during the investigation; (iii) the findings from the investigation; and (iv) if applicable, any consequences imposed pursuant to the *Consequences for QHIN Non-Compliance SOP*.
5. The RCE will provide a draft of the investigation report to the Investigated QHIN. The Complainant, if any, will not receive a copy of the draft investigation report.
6. The Investigated QHIN must provide any feedback on the draft investigation report to the RCE within five (5) business days after the Investigated QHIN's receipt of the draft investigation report. If the Investigated QHIN does not submit feedback within the required time period, the draft investigation report will become final and the Investigated QHIN will be deemed to have accepted the investigation report.
7. If the Investigated QHIN provides feedback within the required time period, the RCE will consider the feedback and issue a final investigation report to the Investigated QHIN within five (5) business days after the RCE's receipt of such feedback or any longer period of time agreed to by the RCE and the Investigated QHIN. The final investigation report may be the same as or different from the draft investigation report. The Complainant, if any, will not receive a copy of the final investigation report.
8. The final investigation report is final and non-appealable, subject to the QHIN's appeal rights in 45 CFR 172.602.
9. In the event that the RCE is unable to make a determination as to whether the Investigated QHIN complied or failed to comply with its obligations under the Common Agreement, SOPs, or QTF, the RCE will notify the Complainant of such finding. If the Complainant is a QHIN, Participant, or Subparticipant, it may elect to pursue the Potential Non-Compliance Matter as a Dispute pursuant to the *Dispute Resolution Process SOP*. If the Complainant pursues a Dispute within fifteen (15) business days after receiving notice from the RCE of the RCE's inability to make a determination on the Potential Non-Compliance Matter, the Complainant is not obligated to participate in an informal conference prior to filing a Dispute.
10. The Investigated QHIN is prohibited from taking any adverse, punitive, or disadvantageous action against the Complainant because they submitted, assisted with, or participated in the filing, investigation, or resolution of a complaint provided such submission, assistance, or participation was undertaken in good faith.

4.2 Deemed Non-Compliance

1. In the following circumstances, the RCE may deem the QHIN in non-compliance without any further investigation and may issue to the QHIN a written finding of deemed non-compliance describing the non-compliant behavior and applicable consequences.

- a. A QHIN's failure to submit the required monthly metrics by the reporting deadline;
 - b. A QHIN's failure to respond to the RCE's escalation of a question within five (5) business days;
 - c. Absent a good faith objection to the RCE's request for information, a QHIN's refusal or failure to provide any requested information in accordance with Section 4.1.2.d of this SOP; or
 - d. A QHIN's failure to comply with a consequence imposed by the RCE.
2. The written finding of deemed non-compliance is final and non-appealable, subject to the QHIN's appeal rights in 45 CFR 172.602.

4.3 Transparency Measures

1. For transparency and to further the understanding of TEFCA's Framework Agreements, SOPs, and QTF, the RCE will publish on the RCE's publicly-facing website an anonymized summary of each investigation report including a summary of the Potential Non-Compliance Matter investigated by the RCE and the outcome of the investigation.
2. For internal administrative and governance purposes, the RCE will maintain a dashboard of all investigations and deemed non-compliance notices. The dashboard will include the name of the Complainant (if any), the name of the Investigated QHIN, the date of the investigation report (if applicable), the findings of the investigation or deemed non-compliance, and, if applicable, the consequences imposed.
 - a. The dashboard will be provided to ONC on a regular basis.
 - b. Updates to the dashboard will be provided to the Governing Council and QHIN Caucus on a regular basis. The dashboard is provided to the Governing Council and QHIN Caucus for information only - not discussion or action. Governing Council and QHIN Caucus will treat such information as Confidential Information.
3. On a quarterly basis, the Governing Council will review the dashboard to determine whether there are any patterns of investigations, non-compliance, and enforcement that suggest a need for modifications to, or further guidance on, the requirements of the Framework Agreements, SOPs, or QTF. The Governing Council's findings, if any, will be shared with ONC.

5 VERSION HISTORY

Version	Revision Date	Section #(s) of Update
Version 1.0	__, 2026	All sections