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# Elements of the Common Agreement

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## WHY IS THE COMMON AGREEMENT NEEDED?

The 21st Century Cures Act calls on the Office of the National Coordinator for Health IT (ONC) to “develop or support a trusted exchange framework, including a common agreement among health information networks nationally.” To that end, the Common Agreement would establish the infrastructure model and governing approach for users in different information exchange networks (“networks”) to securely share clinical information with each other—all under commonly agreed-to expectations and rules, regardless of which network they happen to be in. ONC awarded a cooperative agreement to The Sequoia Project to serve as the Recognized Coordinating Entity (RCE) to develop, update, implement, and maintain the Common Agreement.

The goal of the Common Agreement is to establish a floor of universal interoperability across the country for health care. The Common Agreement would define the baseline legal and technical requirements for secure information sharing on a nationwide scale. This would allow users in different networks to securely share clinical information with each other for specific purposes. By facilitating this exchange, the Common Agreement would create simplified connectivity for use by Individuals, health care providers, health plans, public health agencies, as well as other stakeholders.

The Common Agreement would provide the governing approach necessary to connect and scale the interconnected Qualified Health Information Networks (QHINs)—these would be health information networks that meet certain criteria to demonstrate that they can successfully support the requirements of the Common Agreement. The Common Agreement itself would be a legal agreement that the Recognized Coordinating Entity (RCE) would sign with each QHIN. The RCE would then designate QHINs following a standardized assessment process. Some provisions of the Common Agreement would flow down to Participant and Subparticipant entities via other agreements.

## HOW IS THE COMMON AGREEMENT BEING DEVELOPED?

In July 2021, [ONC and the RCE announced a timeline](#) and process for publishing the Common Agreement in Q1 of 2022.

The RCE has worked closely with ONC to consider stakeholder feedback on previously released Common Agreement materials and has obtained additional feedback on specific issues. Since September 2020, the RCE has received stakeholder feedback through monthly public informational calls, stakeholder meetings, and public feedback sessions on specific topics to inform joint ONC and RCE work to develop the Common Agreement. During that time, the RCE has hosted dozens of events that engaged more than 3,000 people.

ONC and the RCE intend the Common Agreement to build on the successes of existing network capabilities and infrastructure – not replace them. The goal is to fill the gaps of cross-network exchange by keeping what works and creating alignment where there is variation.

**This overview document outlines descriptions of elements that the RCE plans to include in the Common Agreement.** The Common Agreement is under development, so references to it in this overview reflect the current understanding of what it will provide. The purpose of this overview is to provide information to the public about certain topics and solicit feedback to help inform development of the Common Agreement. Furthermore, some elements of the Common Agreement will be further specified in Standard Operating Procedures (SOPs), while the [QHIN Technical Framework](#) (QTF) identifies the functional and technical requirements that QHINs must meet. **The final terms of the Common Agreement may differ from the elements described below.**

The Common Agreement would reference the SOPs and QTF. Attachment 1 identifies the content areas for the initial SOPs. The [QTF](#) and an associated [executive summary](#) have been published and are on the [RCE's QTF webpage](#). The RCE also sought stakeholder input on the QTF.

The Common Agreement is currently under development and will be released in final form in Q1 of 2022. In preparation for release of the finalized Common Agreement, the RCE will share more details and accept input on anticipated elements of the Common Agreement through a set of feedback opportunities announced on the [RCE Community Engagement webpage](#). The RCE is committed to understanding stakeholder perspectives, and the input gathered will inform the drafting of the final Common Agreement. Once ONC approves the final Common Agreement, it will be published publicly.

Sign up for announcements about the Common Agreement, educational webinars, and opportunities to provide input on the RCE [Community Engagement webpage](#).

## WHAT WILL THE ELEMENTS OF THE COMMON AGREEMENT BE?

This section provides an overview of select elements of the Common Agreement. The RCE is previewing these selected topics for further discussion and stakeholder input as the RCE finalizes the Common Agreement in the coming months. After reviewing these elements, stakeholders are encouraged to share feedback during the Common Agreement webinars, via email ([rce@sequoiaproject.org](mailto:rce@sequoiaproject.org)), and via an [online form on the RCE website](#) by October 21, 2021.

### **Below are select Common Agreement elements for stakeholder input:**

1. **Definitions.** To create common understanding, the Common Agreement would define a range of important terms, such as: QHINs, Participants, Subparticipants, Exchange Purposes, TEFCA Information, Required Flow-Downs, and TEFCA Security Incident. Attachment 2 includes a subset of select definitions for stakeholder feedback, which are discussed in general terms below. Throughout this document all defined terms are capitalized.
2. **Exchange Purposes.** The term Exchange Purposes identifies the reasons for which information could be requested and shared through QHIN-to-QHIN exchange. Initially, QHINs would support the following Exchange Purposes:

- Treatment,
- Payment,
- Health Care Operations,
- Public Health,
- Benefits Determination, and
- Individual Access Services.

The Common Agreement would specify the requests, Uses, Disclosures, and responses that would be permitted, prohibited, and required. This would include the following, provided not prohibited by Applicable Law:

- **Requests:** TEFCA requests would be transmitted via a QHIN's Connectivity Services and consistent with the requirements of the QTF, including when queries are made for health information.
  - QHIN-to-QHIN exchange may only be initiated for one of the specified Exchange Purposes.
  - Only certain QHINs, Participants, or Subparticipants could make requests for each Exchange Purpose. Specifically, a QHIN, Participant, or Subparticipant may only request, Use, or Disclose TEFCA Information for a specific Exchange Purpose if the QHIN, Participant, or Subparticipant is the type of person or entity that is described in the definition of the applicable Exchange Purpose. For example, only a health care provider as described in the definition of Treatment could request information for the Exchange Purpose of Treatment.<sup>1,2</sup>
- **Uses and Disclosures** would adhere to the Common Agreement privacy and security requirements and any applicable privacy notices.
- **Responses:** In most cases, QHINs, Participants, and Subparticipants would be required to respond to a request for certain health information for any of the Exchange Purposes. Responses would not be required by the Common Agreement if providing the information is prohibited by Applicable Law or the Common Agreement. Also, there would be specific exceptions where a response is permitted but not required by the Common Agreement:
  - If Signatory is a Public Health Authority;

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<sup>1</sup> As another example, a provider of social services that is not a health care provider would, in almost all instances, not be able to request data for Treatment, Payment, or Health Care Operations. However, a health care provider may disclose TEFCA Information to a social services agency for treatment purposes, consistent with the HIPAA Privacy Rule. Such providers of social services could request information if they did so as Individual Access Services Providers or if they were serving as a contractor to a health care provider, for example.

<sup>2</sup> Exchange pursuant to one of the Framework Agreements does not preclude the electronic exchange of information through other mechanisms and for other purposes (e.g., other non-Common Agreement agreements allowing the exchange of protected health information between community-based organizations and health care providers, as permitted under the HIPAA Privacy Rule, or the exchange of Controlled Unclassified Information between government agencies and others in compliance with statutory requirements for the transmission of such information).

- If Signatory is a governmental agency that determines non-health care benefits, including such an agency’s agent(s)/contractor(s);
- If Signatory is a Non-HIPAA Entity provider of Individual Access Services;
- If the reason asserted for the request is Individual Access Services and the information would not be required to be provided to an Individual pursuant to 45 CFR § 164.524(a)(2), regardless of whether Signatory is a Non-HIPAA Entity, a Covered Entity, or a Business Associate;
- If the requested information is not Required Information (as described in Section 5 “TEFCA Information and Required Information” below), provided such response would not otherwise violate the terms of this Common Agreement; or
- If Signatory is a federal agency, to the extent that the requested Disclosure of Required Information is not permitted under Applicable Law (e.g., it is Controlled Unclassified Information as defined at 32 CFR Part 2002 and the party requesting it does not comply with the applicable policies and controls that the federal agency adopted to satisfy its requirements).

For the purposes of QHIN-to-QHIN exchange, the terms “Treatment,” “Payment,” and “Health Care Operations” generally would have the same meaning as they do under the HIPAA Privacy Rule and would apply to all TEFCA Information, regardless of whether or not the parties to exchange are HIPAA Covered Entities<sup>3</sup> or Business Associates.<sup>4</sup> The Public Health Exchange Purpose would include requests for Uses and Disclosures of information by Public Health Authorities that are consistent with the HIPAA Privacy Rule and other Applicable Law. The Benefits Determination Exchange Purpose would support governmental agencies that need information to determine whether a person qualifies for non-health government benefits in a manner that is consistent with the HIPAA Privacy Rule and other Applicable Law.

The Common Agreement anticipates the use of consumer-facing applications that would assist Individuals in obtaining access to their health information. This Exchange Purpose is called Individual Access Services. To the extent permitted by law, Individuals could use an account with a connected consumer-facing application or platform, prove who they are, and request their health information from entities connected via QHIN-to-QHIN exchange.<sup>5</sup>

At this time, only the six Exchange Purposes described above would be allowed under the Common Agreement; the RCE plans to work with stakeholders to identify additional Exchange Purposes over time, as appropriate. For example, requesting or sending information to support biomedical research could be identified as an Exchange Purpose in

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<sup>3</sup> For more information about the term HIPAA Covered Entity, see: 45 CFR 160.103 (definition of “covered entity”) and <https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html>.

<sup>4</sup> See 45 CFR 160.103 (definition of “business associate”). See also Direct Liability of Business Associates Fact Sheet at <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html>.

<sup>5</sup> Entities will not need to respond to Individual Access Services data requests if they meet an exception, which will include, for example, if they are themselves a non-HIPAA Entity provider of Individual Access Services, or if they are prohibited from doing so by law.

a future version of the Common Agreement, if amendments with appropriate requirements and protections are adopted in the Common Agreement.

3. **Participants and Subparticipants.** The Common Agreement would enable a network of networks of high-performing, reliable, and secure QHINs to share health information. Each of the QHINs would support exchange on behalf of the respective Participants with which they have a separate data sharing agreement. In turn, Participants could enter into information sharing agreements with one or more Subparticipants. The network of networks would have at least three layers consisting of QHINs, Participants, and Subparticipants. Stakeholders would connect at the point that is most appropriate for them. For example, a health information exchange, health IT software developer, health care system, payer, or federal agency could each be a Participant. Subparticipants could include a physician practice, hospital, pharmacy, or public health agency, among others.
4. **Required Flow-Down Provisions.** The Common Agreement lays out certain provisions that QHINs would be required to include in their Framework Agreements with Participants and that Participants would be expected to include in their agreements with any Subparticipants. These would be called “Required Flow-Down” provisions. The required flow-down provisions would address: cooperation and nondiscrimination; confidentiality; utilization of the RCE Directory Service; Uses, Disclosures, and responses; Individual Access Services; privacy; security; and other general obligations.
5. **TEFCA Information and Required Information.** For purposes of the Common Agreement, TEFCA Information would be defined as any information that is exchanged between QHINs for one or more of the Exchange Purposes as permitted under any of the Framework Agreements (including the Common Agreement).
  - The requirements related to the Uses and Disclosures of information mentioned above in Section 2 “Exchange Purposes” would apply to TEFCA Information.
  - It is anticipated that most of the QHINs, Participants, and Subparticipants would be subject to the HIPAA Rules, so much of the TEFCA Information being exchanged pursuant to the Framework Agreements would also meet the HIPAA Rules’ definition of electronic Protected Health Information (ePHI). The Common Agreement and its Required Flow-Down provisions would not replace the obligations of HIPAA Covered Entities and HIPAA Business Associates to comply with the HIPAA Rules. Rather, they would extend many of the requirements of the HIPAA Rules to health care providers that are not Covered Entities, as discussed below.
  - TEFCA Information may also include HIPAA de-identified information, which, by definition, is not subject to the HIPAA Privacy Rule. We note, however, that the Framework Agreements (including the Common Agreement) would not extend the HIPAA Privacy Rule protections to HIPAA de-identified information.
  - TEFCA Information would not be limited to health information, in that there may be instances where non-health information is sent between QHINs for an Exchange Purpose. For example, a Non-HIPAA Entity Individual Access Service Provider

that is not a health care provider may request information from another Non-HIPAA Entity Individual Access Service Provider that is not a health care provider.

- A QHIN, Participant, or Subparticipant that receives a request would be obligated to provide all Required Information that is available for the Exchange Purpose asserted, unless providing the Required Information is prohibited by Applicable Law or one of the Framework Agreements. Required Information would generally be the ePHI (as defined by HIPAA) that is created, received, transmitted, or retained by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement.<sup>6</sup>
- There are exceptions to this requirement to respond, as specified in Section 2 “Exchange Purposes,” above.
- The Framework Agreements would not relieve any QHIN, Participant, or Subparticipant from its obligations under other Applicable Laws. For example, as noted elsewhere in this document, entities that are subject to the HIPAA Rules or more restrictive laws and regulations would still be required to comply with those obligations, regardless of the obligations imposed by the Framework Agreements.

6. **Governing Approach to Exchange Activities Under the Common Agreement.** The Common Agreement will specify the way in which QHINs, Participants, and Subparticipants may participate in oversight of activities under the Common Agreement and how the document may change. The governing bodies will serve as a resource to the RCE and provide a forum for discussion of issues affecting exchange activities that may arise under the Common Agreement. The Common Agreement will create a Transitional Council as an interim body for a 12-month period, followed by the permanent Governing Council. In addition, a QHIN Caucus and Participant/Subparticipant Caucus will be established, which will elect members to the Governing Council. Advisory Groups could also be established, as needed, to seek feedback from distinct groups of stakeholders.

Among other activities, these deliberative bodies will be engaged in reviewing proposed amendments to the Common Agreement, the QTF, and the SOPs in accordance with the Common Agreement’s specified change management process. The governing approach will also provide oversight for resolution of disputes, following the dispute resolution process that will be part of the Common Agreement. Lastly, ONC will fulfill its role as required by the 21<sup>st</sup> Century Cures Act, including overseeing the work of the RCE under the Cooperative Agreement. ONC approval is required for amendments to the Common Agreement, the SOPs, and the QTF.

7. **QHIN Designation and Eligibility Criteria.** Only the RCE would be able to Designate a QHIN under the Common Agreement. The RCE is establishing an application and assessment process to Designate QHINs. The Common Agreement would include specific QHIN eligibility criteria that generally address:

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<sup>6</sup> See full definition of Required Information in the Appendix.

- The ability to perform all of the required functions of a QHIN, as identified in the QTF;
- The legal structure and governing approach for the QHIN; and
- Demonstrated resources and infrastructure necessary to support a reliable and trusted network.

The RCE requests feedback on the specific QHIN Designation Eligibility Criteria, which will be released for stakeholder input.

8. **Cooperation and Nondiscrimination.** The Common Agreement would specify expectations of QHINs, Participants, and Subparticipants that would ensure that all parties cooperate in certain aspects of exchange. This includes timely responses to inquiries, notification of persistent and widespread connectivity failures, support in resolving issues, and sharing information regarding cybersecurity risks. In addition, QHINs, Participants, and Subparticipants would be prohibited from limiting interoperability with any other QHIN, Participant, Subparticipant, or Individual in a discriminatory manner.
9. **RCE Directory Service.** The RCE would maintain an RCE Directory Service to support exchange of information between and among QHINs, Participants, and Subparticipants. The Common Agreement would identify the rights and limits on use of the RCE Directory Service. For example, the information contained in the RCE Directory Service is prohibited from being used for marketing purposes unless that marketing is merely incidental to an effort to expand or improve connectivity via the Common Agreement.
10. **Individual Access Services (IAS).** IAS would be the services any QHIN, Participant, or Subparticipant provide to an Individual to satisfy that Individual's request to access, inspect, or obtain a copy of that Individual's TEFCFA Information that is then maintained by any QHIN, Participant, or Subparticipant. A QHIN, Participant, or Subparticipant would be allowed, but not required, to offer IAS to Individuals with whom they have a Direct Relationship. Each QHIN, Participant, and Subparticipant that elects to offer IAS to Individuals would be an Individual Access Services Provider (IAS Provider). IAS Providers would be allowed to make requests on behalf of Individuals for data from all other QHINs, Participants, or Subparticipants using the IAS Exchange Purpose. Those QHINs, Participants, and Subparticipants that receive such requests and hold that Individual's Required Information would then be obligated to respond with that data, unless they meet an exception, as described in Section 2 "Exchange Purposes," above.
  - The Common Agreement would specify the additional privacy and security requirements that a QHIN, Participant, or Subparticipant would be required to adhere to if it chooses to become an IAS Provider. The Common Agreement's IAS requirements would specify the elements of a written privacy notice for such IAS Providers, which would include a description of the need to obtain express consent from Individuals regarding the way their information will be accessed, exchanged, Used, or Disclosed by the IAS Provider. In addition, the Common Agreement would specify Individual rights that IAS Providers would need to provide, such as the Individual's right to have deleted all of their individually identifiable



information maintained by an Individual Access Service Provider and the right to obtain an export of their data in a computable format. Finally, IAS Providers would need to implement security requirements related to encryption and certain security incident notifications.

11. **Privacy and Security.** The Common Agreement will promote strong privacy and security protections. Most connected entities will be HIPAA Covered Entities or their Business Associates, and thus already required to comply with the HIPAA Privacy, Security, and Breach Notification Rule requirements. To ensure that privacy and security protections cover certain entities that are not subject to the HIPAA Rules, the Common Agreement would require such Non-HIPAA Entities to protect TEFCA Information that is individually identifiable in substantially the same manner as HIPAA Covered Entities protect PHI, including having to comply with the HIPAA Security Rule and most provisions of the HIPAA Privacy Rule. This alignment will promote trust.

QHINs would be expected to meet and maintain third-party certification to an industry-recognized cybersecurity framework and undergo annual security assessments. The Common Agreement would require flow-down contract provisions for all Participants and Subparticipants to undertake, at a minimum, security measures that align with the HIPAA Security Rule, even if they are not HIPAA Covered Entities or Business Associates. The Common Agreement would also specify expectations for security incident notifications affecting QHIN-to-QHIN exchange that would apply to QHINs and flow down to Participants and Subparticipants. These provisions would be designed to avoid conflict with Applicable Law and duplicative notification requirements. The RCE would actively facilitate information security activities, with the support of a Cybersecurity Council drawn from participating QHINs.

12. **Special Requirements (including Consent).** As noted above, Uses and Disclosures of TEFCA Information would be subject to the limitations of Applicable Law including HIPAA and state laws. The Common Agreement would not require QHINs, Participants, and Subparticipants that are not IAS Providers to obtain Individual consent to Use or Disclose TEFCA Information except to the extent they would be required to do so under Applicable Law. The HIPAA Privacy Rule permits, but does not require, a Covered Entity to obtain patient consent for Uses and Disclosures of Protected Health Information for Treatment, Payment, and Health Care Operations activities. The Common Agreement would require IAS Providers to obtain express consent from Individuals for, among other things, how the Individual's information may be accessed, exchanged, Used, and/or Disclosed, including whether that information may be sold.

- Many municipal governments and states have laws that require patient consent.<sup>7</sup> If municipal or state law requires that an Individual's consent be obtained before a health care provider Discloses an Individual's identifiable information for Treatment, then the Common Agreement does not change that requirement. Such a provider would obtain consent from an Individual before disclosing that

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<sup>7</sup> <https://dashboard.healthit.gov/datadashboard/documentation/state-health-it-privacy-consent-law-policy-data-documentation.php>

Individual's information to others under the Common Agreement. Furthermore, given the state law, the provider would not be required to respond to TEFCA Information requests if that provider has not obtained the proper consent.

This approach would allow for local variability and choice related to consent. The Common Agreement would not create a national opt-in or opt-out registry or process regarding the Use of an Individual's information or the Disclosure of an Individuals' information from one provider or entity to another. In situations where consent documents may be shared, the QTF has proposed a mechanism for QHINs, Participants, Subparticipants, and Individuals to share such electronic documents with each other.

The Common Agreement would not supersede a Covered Entity's obligations under the HIPAA Privacy Rule to obtain an Individual's authorization (as defined in the HIPAA Privacy Rule) when required.

13. **Fees.** The Common Agreement is expected to include a provision that prohibits a QHIN from charging fees to other QHINs with respect to activities under the Common Agreement. QHINs would not be prohibited from charging fees to Participants.

## HOW CAN STAKEHOLDERS PROVIDE FEEDBACK ON THE COMMON AGREEMENT?

The RCE welcomes feedback on elements of the Common Agreement. The RCE will conduct a stakeholder engagement process that will include public webinars and website content that will enable interested parties to learn more about topics covered in the Common Agreement with opportunities to share their feedback during webinars, via email ([rce@sequoiaproject.org](mailto:rce@sequoiaproject.org)), and via an [online form on the RCE website](#) by October 21, 2021.

The [draft of the QHIN Technical Framework \(QTF\)](#) and its executive summary were also published for stakeholder input and are available on the [RCE's webpage for the QTF](#).

The webinars on the Common Agreement will provide more information and provide an opportunity for input. The following topics will be presented:

- Change Management,
- Confidentiality and Accountability,
- Exchange Purposes and Permitted Requests,
- Fees,
- Governing Approach,
- Individual Access Services
- Permitted Uses and Disclosures,
- Privacy,
- QHIN Eligibility Criteria,

- Required Responses, and
- Security.

The RCE is committed to routinely convening stakeholders to support continued engagement. Sign up for announcements about the Common Agreement and upcoming feedback opportunities on the RCE [Community Engagement webpage](#).

## ATTACHMENT 1: TOPICS COVERED BY STANDARD OPERATING PROCEDURES

Signatories to the Common Agreement would also be expected to adhere to Standard Operating Procedures (SOPs), including as amended by the change management process. The initial SOPs would be:

- Standard Operating Procedure (SOP): Advisory Groups,
- Standard Operating Procedure (SOP): Conflicts of Interest,
- Standard Operating Procedure (SOP): Dispute Resolution Process,
- Standard Operating Procedure (SOP): Governing Council,
- Standard Operating Procedure (SOP): QHIN Eligibility Criteria, Onboarding, and Designation,
- Standard Operating Procedure (SOP): QHIN Security Requirements for the Protection of TEFCA Information, and
- Standard Operating Procedure (SOP): Transitional Council.

## ATTACHMENT 2: DRAFT DEFINITIONS OF COMMON AGREEMENT TERMS USED IN THIS DOCUMENT

- **Applicable Law:** all federal, state, local, or tribal laws and regulations then in effect and applicable to the subject matter herein.
- **Benefits Determination:** a determination made by any federal, state, local, or tribal agency, instrumentality, or other unit of government as to whether an Individual qualifies for government benefits for any purpose other than health care (for example, Social Security disability benefits) to the extent permitted by Applicable Law. Disclosure of TI for this purpose may require an authorization that complies with Applicable Law.
- **Business Associate:** has the meaning assigned to such term at 45 CFR § 160.103.
- **Connectivity Services:** the technical services provided by a QHIN consistent with the requirements of the then-applicable QHIN Technical Framework and pursuant to this Common Agreement with respect to all Exchange Purposes.
- **Covered Entity:** has the meaning assigned to such term at 45 CFR § 160.103.
- **Cybersecurity Council:** the council established by the RCE to enhance cybersecurity commensurate with the risks to QHIN-to-QHIN exchange, as more fully set forth in an SOP.
- **Designation (including its correlative meanings “Designate,” “Designated,” and “Designating”):** the RCE’s written confirmation to ONC that Signatory has satisfied all the requirements of the Common Agreement, the QHIN Technical Framework, and all applicable SOPs and is now a QHIN.
- **Direct Relationship:** a relationship between (1) an Individual and (2) a QHIN, Participant, or Subparticipant, that arises when the QHIN, Participant, or Subparticipant, as applicable, offers services to that person in connection with one or more of the Framework Agreements, and the Individual agrees to receive such services.
- **Disclosure (including its correlative meanings “Disclose,” “Disclosed,” and “Disclosing”):** the release, transfer, provision of access to, or divulging in any manner of TI outside the entity holding the information.
- **Dispute:** means (i) a disagreement about any provision of this Common Agreement, including any Standard Operating Procedure, the QHIN Technical Framework, and all other attachments, exhibits, and artifacts incorporated by reference; or (ii) a concern or complaint about the actions, or any failure to act, of Signatory, the RCE, or any other QHIN or another QHIN’s Participant(s).
- **Downstream Subparticipant:** a Subparticipant (as defined below) that has entered into a Downstream Subparticipant Agreement to receive services from another Subparticipant

(referred to as the “Upstream Subparticipant”) to send and/or receive TEFCA Information (TI).

- **Downstream Subparticipant Agreement:** an agreement that incorporates all of the Required Flow-Downs of this Common Agreement and is between a Subparticipant (referred to as the “Upstream Subparticipant”) and one or more Subparticipants (each a “Downstream Subparticipant”) pursuant to which each of the Downstream Subparticipant(s) may use the services of the Upstream Subparticipant to send and/or receive TEFCA Information for one or more Exchange Purposes; provided, however, that any provisions of said agreement that permit or require activities other than those required or permitted by the Common Agreement shall not be deemed part of the Downstream Subparticipant Agreement as defined herein. For example, if the agreement provides for transmission of information for reasons other than the Exchange Purposes, the provisions governing such activities shall not be deemed part of the Participant-Subparticipant Agreement as defined herein. Any Subparticipant may enter into a Downstream Subparticipant Agreement.
- **Exchange Purpose(s):** means the reason for a request, Use, Disclosure, or response transmitted via QHIN-to-QHIN exchange as one step in the transmission. Exchange Purposes are: Treatment, Payment, Health Care Operations, Public Health, Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Standard Operating Procedure (SOP) adopted after \_\_\_\_\_, 202\_\_\_\_, each to the extent permitted under Applicable Law, under all applicable provisions of this Common Agreement, and, if applicable, under the SOP that authorized the Exchange Purpose.
- **Fees:** any present or future obligation to pay money or provide any other thing of value charged by a QHIN to another QHIN in connection with the activities conducted under the Framework Agreements.
- **Framework Agreement(s):** any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, and/or a Downstream Subparticipant Agreement, as applicable.
- **Health Care Operations:** has the meaning assigned to such term at 45 CFR § 164.501, except that this term shall apply to a healthcare provider regardless of whether the healthcare provider is a Covered Entity.
- **Health Information Network (HIN):** has the meaning assigned to the term “*Health Information Network or Health Information Exchange*” in the Information Blocking Regulations at 45 § CFR 171.102.
- **HIPAA:** the Health Insurance Portability and Accountability Act of 1996 codified at 42 U.S.C. § 300gg, 29 U.S.C. § 1181 *et seq.*, 42 U.S.C. § 1320d *et seq.*, the Health Information Technology for Economic and Clinical Health (HITECH) Act codified at 42 U.S.C. § 17921 *et seq.*, and 42 U.S.C. § 17931 *et seq.*
- **HIPAA Rules:** the regulations set forth at 45 CFR Parts 160, 162, and 164.

- **HIPAA Privacy Rule:** the regulations set forth at 45 CFR Parts 160 and 164, Subparts A and E.
- **HIPAA Security Rule:** the regulations set forth at 45 CFR Parts 160 and 164, Subpart C.
- **Individual:** one or more of the following:
  1. An individual as defined by 45 CFR 160.103;
  2. Any other natural person who is the subject of the TEFCA Information being requested, Used, or Disclosed;
  3. A person who legally acts on behalf of a person described in paragraphs (1) or (2) of this definition in making decisions related to healthcare as a personal representative, in accordance with 45 CFR 164.502(g);
  4. A person who is a legal representative of and can make healthcare decisions on behalf of any person described in paragraphs (1) or (2) of this definition; or
  5. An executor, administrator, or other person having authority to act on behalf of a deceased person described in paragraphs (1) or (2) of this section or the individual's estate under Applicable Law.
- **IAS Provider:** Each QHIN, Participant, and Subparticipant that offers Individual Access Services.
- **Individual Access Services:** with respect to the Exchange Purposes definition, the optional services provided, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's TI that is then maintained by or for any QHIN, Participant, or Subparticipant.
- **Non-HIPAA Entity (NHE):** a QHIN, Participant, or Subparticipant that is neither a Covered Entity nor a Business Associate under HIPAA with regard to activities under this Common Agreement.
- **ONC:** the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology.
- **Participant:** a U.S. Entity, or a non-U.S. Entity if and to the extent permitted by an SOP, regardless of whether the entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement whereby the QHIN agrees to transmit and receive TI via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes. Without limitation of the foregoing, a health information exchange, health IT developer, health care system, payer, or federal agency could each be a Participant.
- **Participant-QHIN Agreement:** An agreement that incorporates all of the Required Flow-Downs of this Common Agreement and is between a QHIN and one or more Participants; provided, however, that any provisions of said agreement that permit or

require activities other than those required or permitted by the Common Agreement shall not be deemed part of the Participant-QHIN Agreement as defined herein. For example, if the agreement provides for transmission of information for reasons other than the Exchange Purposes, the provisions governing such activities shall not be deemed part of the Participant-QHIN Agreement as defined herein. In the event of any conflict or inconsistency between or among Applicable Law, the Participant-QHIN Agreement, and any other terms and conditions, the following shall be the order of precedence to the extent of such conflict or inconsistency: (i) Applicable Law, (ii) the provisions of the Participant-QHIN Agreement that are Required Flow-Downs under this Common Agreement, (iii) to the extent applicable, the QHIN Technical Framework (QTF); (iv) to the extent applicable, the SOPs, and (v) any other terms and conditions agreed to by the parties.

- **Participant-Subparticipant Agreement:** An agreement that incorporates all of the Required Flow-Downs of this Common Agreement and is between a Participant and one or more Subparticipants that may receive the services of the Participant to send and/or receive TI; provided, however, that any provisions of said agreement that permit or require activities other than those required or permitted by the Common Agreement shall not be deemed part of the Participant-Subparticipant Agreement as defined herein. For example, if the agreement provides for transmission of information for reasons other than the Exchange Purposes, the provisions governing such activities shall not be deemed part of the Participant-Subparticipant Agreement as defined herein. In the event of any conflict or inconsistency between or among Applicable Law, the Participant-Subparticipant Agreement, and any other terms and conditions, the following shall be the order of precedence to the extent of such conflict or inconsistency: (i) Applicable Law, (ii) the provisions of the Participant-Subparticipant Agreement that are Required Flow-Downs under this Common Agreement, (iii) to the extent applicable, the QTF; (iv) to the extent applicable, the SOPs; and (v) any other terms and conditions agreed to by the parties.
- **Payment:** has the meaning assigned to such term at 45 CFR § 164.501.
- **Protected Health Information (PHI) and Electronic Protected Health Information (ePHI):** have the meanings assigned to such terms at 45 CFR § 160.103.
- **Public Health:** with respect to the definition of Exchange Purposes, a request, Use, Disclosure, or response permitted under the HIPAA Rules and other Applicable Law for public health activities and purposes involving a Public Health Authority, where such public health activities and purposes are permitted by Applicable Law, including a Use or Disclosure permitted under 45 CFR §164.512(b) and 45 CFR §164.514(e). For the avoidance of doubt, a Public Health Authority may request, Use, and Disclose TI hereunder for the Exchange Purpose of Public Health to the extent permitted by Applicable Law and the Framework Agreements.
- **Public Health Authority:** has the meaning assigned to such term at 45 CFR §164.501.



- **QHIN Technical Framework (QTF):** the document approved pursuant to the Common Agreement and incorporated by reference into this Common Agreement, including as may be amended, that may include: (1) technical requirements, functional requirements, and privacy and security related considerations required for the exchange of TI between QHINs; (2) internal-QHIN functional requirements; (3) technical, privacy, and security flow-down requirements from the QHIN to the Participants and/or Subparticipants (if any) in addition to the privacy and security Required Flow-Downs in the Common Agreement; and (4) operational considerations that enable the exchange of TI between and among QHINs.
- **Qualified Health Information Network (QHIN):** a Health Information Network that is a U.S. Entity, or non-U.S. Entity if and to the extent permitted by an SOP, that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.
- **RCE Directory Service:** a technical service provided by the RCE that enables QHINs, Participants, and Subparticipants to share directory information associated with other QHINs, Participants, and Subparticipants in order to enable the exchange of TI under the Common Agreement. The then-current technical endpoints and other identifying information of QHINs, Participants, and Subparticipants are included and maintained as part of the RCE Directory Service.
- **Recognized Coordinating Entity (RCE):** the entity selected by ONC that will enter into this Common Agreement with QHINs in order to impose, at a minimum, the requirements of the Common Agreement, including the SOPs and the QHIN Technical Framework, on the QHINs and administer such requirements on an ongoing basis. The RCE is a Party to this Common Agreement.
- **Required Flow-Down(s):** the rights and obligations set forth within this Common Agreement that Signatory is required to incorporate in its Participant-QHIN Agreements and that Signatory is required to obligate its Participants to include in their Subparticipant Agreements and that Subparticipants are obligated to impose on their Downstream Subparticipants, if any, through their Downstream Subparticipant Agreements. **Provisions of this Common Agreement containing such rights and obligations are identified in the section or applicable subsection title as “(Required Flow-Down(s)).”**
- **Required Information:** ePHI created, received, transmitted, or retained by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement:
  - (i) Regardless of whether the QHIN, Participant, or Subparticipant is a Covered Entity or a Business Associate; and
  - (ii) Regardless of whether the information is or has already been transmitted via QHIN-to-QHIN exchange; provided, however, that a QHIN, Participant, or Subparticipant shall not be required to Disclose either of the following as Required Information:

- (a) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; or
  - (b) psychotherapy notes (as defined at 45 CFR 164.501).
- **Standard Operating Procedure(s) or SOP(s):** a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into this Common Agreement to provide detailed information or requirements related to the exchange activities under the Common Agreement, including all amendments thereto and any new SOPs that are adopted pursuant to the Common Agreement. SOPs will be adopted to address the application process, the Onboarding process, and other operational processes.
  - **Subparticipant:** a U.S. Entity, or a non-U.S. Entity if and to the extent permitted by an SOP, regardless of whether the entity is a Covered Entity or Business Associate, that has entered into either: (i) a Participant-Subparticipant Agreement to use the services of a Participant to send and/or receive TI or (ii) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used to send and/or receive TI.
  - **TEFCA Information (TI):** any information that is exchanged between QHINs for one or more of the Exchange Purposes pursuant to any of the Framework Agreements.
  - **TEFCA Security Incident(s):**
    1. An unauthorized acquisition, access, Disclosure, or Use of unencrypted TI whether in transit or at rest, but **NOT** including the following:
      - (i) Any unintentional acquisition, access, or Use of TI by a workforce member or person acting under the authority of a QHIN, Participant, or Subparticipant, if such acquisition, access, or Use was made in good faith and within the scope of authority and does not result in further Use or Disclosure in a manner not permitted under Applicable Law and this Common Agreement.
      - (ii) Any inadvertent Disclosure by a person who is authorized to access TI at a QHIN, Participant, or Subparticipant to another person authorized to access TI at the same QHIN, Participant, or Subparticipant, or organized health care arrangement in which a Covered Entity participates, and the information received as a result of such Disclosure is not further Used or Disclosed in a manner not permitted under Applicable Law and this Common Agreement.
      - (iii) A Disclosure of TI where a QHIN, Participant, or Subparticipant has a good faith belief that an unauthorized person to whom the Disclosure was made would not reasonably have been able to retain such information.
      - (iv) TI that has been de-identified in accordance with the standard at 45 C.F.R. § 164.514(a).

2. Other security events (e.g., ransomware attacks), as set forth in an SOP, that prevent the affected QHIN, Participant, or Subparticipant from responding to requests for information as required under this Agreement or otherwise adversely affect their participation in QHIN-to-QHIN exchange (e.g., ransomware attack).
- **Treatment:** has the meaning assigned to such term at 45 CFR § 164.501.
  - **U.S. Entity/Entities:** any corporation, limited liability company, partnership, or other legal entity that meets all of the following requirements:
    1. The entity is organized under the laws of a state or commonwealth of the United States or the federal law of the United States and is subject to the jurisdiction of the United States and the state or commonwealth under which it was formed;
    2. The entity’s principal place of business, as determined under federal common law, is in the United States; and
    3. None of the entity’s directors, officers, or executives, and none of the owners with a five percent (5%) or greater interest in the entity, are listed on the Specially Designated Nationals and Blocked Persons List published by the United States Department of the Treasury’s Office of Foreign Asset Control or on the Office of Inspector General list of excluded persons.
    4. If applicable, other requirements set forth in an SOP which specifically addresses foreign ownership.
  - **Use (including correlative uses/tenses, such as “Used,” “Uses,” and “Using”):** with respect to TI, means the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.