



Standard Operating Procedure (SOP):
Means To Demonstrate U.S.
Ownership and Control of a Qualified
Health Information Network (QHIN)

Applicability: Entities seeking to be Designated as a QHIN; QHINs

1 COMMON AGREEMENT REFERENCES

Common Agreement Section 1.1 – U.S. Entity/Entities Definition:

U.S. Entity/Entities: Any corporation, limited liability company, partnership, or other legal entity that meets all of the following requirements:

- (i) 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;
- (ii) The entity’s principal place of business, as determined under federal common law, is in the United States; and
- (iii) None of the entity’s directors, officers, or executives, and none of the owners with a 5 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 Department of Health and Human Services, Office of Inspector General’s List of Excluded Individuals/Entities.

Common Agreement Section 4.1(i):

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 is set forth in an SOP.

Capitalized terms used below without definitions shall have the respective meanings assigned to such terms in the Common Agreement and the QHIN Technical Framework.

2 PURPOSE

This SOP sets forth the means by which an entity seeking to be Designated as a QHIN, (the “Applicant”), shall demonstrate that it satisfies the requirements of Section 4.1(i) of the Common Agreement. It also identifies the parameters under which a QHIN may permissibly have limited ownership or control by a Non-U.S. Person(s) or Non-U.S. Entity(ies). This is important because the U.S. healthcare system is part of the nation’s critical infrastructure as determined by the Critical Infrastructure Security Agency, which is a part of the Department of Homeland Security. QHINs are required to protect the privacy and security of TEFCO Information (TI) and to support the exchange of TI in support of the U.S. healthcare system. Therefore, it is important that QHINs not be owned or controlled by those who might seek to do harm to the United States or misuse TI.

3 DEFINITIONS

“Direct Ownership Interest” means an Ownership Interest other than an Indirect Ownership Interest.

“Entity” means a corporation, trust, partnership, limited liability company or partnership, joint venture, unincorporated organization, governmental authority or any agency or political subdivision thereof, or other entity.

“Five Eyes Countries” means the countries that make up the Five Eyes Oversight and Review Council (FIORC), which include Australia, Canada, New Zealand, the United Kingdom, and the United States, as of September 1, 2022.¹

“Foreign Control” means a Non-U.S. Person(s) or Non-U.S. Entity(ies) has (have) the direct or indirect power, whether or not exercised, to direct or decide matters materially affecting the Applicant’s ability to function as a QHIN in a manner that presents a national security risk.

“Indirect Ownership Interest” means an Ownership Interest in an entity that has an Ownership Interest in the Applicant entity. This term includes an Ownership Interest in any entity that has an Indirect Ownership Interest in the Applicant entity. The amount of Indirect Ownership Interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation which owns 80 percent of the stock of the Applicant, A’s interest equates to an 8 percent Indirect Ownership Interest in the Applicant. Conversely, if B owns 80 percent of the stock of a corporation which owns 5 percent of the stock of the Applicant, B’s interest equates to a 4 percent Indirect Ownership Interest in the Applicant.

“Non-U.S. Entity” means any Entity that is not a U.S. Entity as defined in the Common Agreement.

“Non-U.S. Person” means any individual who is not a U.S. Qualified Person.

“Ownership Interest” means the possession of equity in the capital, the units, the stock, or the profits of an entity.

“U.S. Qualified Person” means those individuals who are U.S. nationals and citizens at birth as defined in 8 USC 1401, U.S. nationals but not citizens of the United States at birth as defined in 8 USC 1408, lawful permanent residents of the United States as defined in Immigration and Nationality Act, and non-immigrant aliens who are hired by a U.S. Entity as an employee in a specialty occupation pursuant to an H-1B Visa.

¹ Office of the Director of National Intelligence webpage on FIORC: <https://www.dni.gov/index.php/ncsc-how-we-work/217-about/organization/icig-pages/2660-icig-fiorc>

4 STANDARD

4.1 An Entity seeking to be Designated as a QHIN will be considered to be owned or controlled by any Non-U.S. Person(s) or Non-U.S. Entity(-ies) and automatically disqualified from such Designation in the following situations:

(i) If any of the Applicant’s directors, officers, or executives or any Entity or individual with a Direct or Indirect Ownership Interest in the Applicant of 5% or greater is any of the following:

a. Listed on the United States Department of the Treasury, Office of Foreign Assets Control (OFAC) list of “Specially Designated Nationals” or “SDNs.” The SDN list is a list of individuals and companies owned or controlled by, or acting for or on behalf of, countries that OFAC has identified as a threat, as well as individuals, groups, and entities, such as terrorists and narcotics traffickers, designated under programs that are not country-specific. OFAC keeps this list current, and it is publicly available at <https://home.treasury.gov/policy-issues/financial-sanctions/specially-designated-nationals-and-blocked-persons-list-sdn-human-readable-lists>; or

b. A citizen or legal resident of a country listed on the OFAC Sanctions Program and Country Information page available at <https://home.treasury.gov/policy-issues/financial-sanctions/sanctions-programs-and-country-information>; or

c. Listed on the Department of Health and Human Services, Office of Inspector General’s List of Excluded Individuals. OIG keeps this list current, and it is publicly available at https://oig.hhs.gov/exclusions/exclusions_list.asp.

(ii) If any Non-U.S. Entity has a Direct or Indirect Ownership Interest in the Applicant of 50% or greater, unless such Non-U.S. Entity is organized under the law of a Five Eyes Country other than the United States.

(iii) If any Non-U.S. Person has a Direct or Indirect Ownership Interest in the Applicant of 50% or greater, unless such Non-U.S. Person is a citizen of a Five Eyes Country other than the United States.

(iv) If any combination of Non-U.S. Person(s) and/or Non-U.S. Entity(ies) has an aggregate Direct or Indirect Ownership Interest of 50% or greater in the Applicant, unless such Non-U.S. Person(s) and Non-U.S. Entity(ies) are citizens of or organized under the laws of Five Eyes Countries other than the United States.

4.2 If the Applicant is not subject to automatic disqualification pursuant to the above criteria and: (a) has any Non-U.S. Person with a Direct or Indirect Ownership Interest of 20% or greater; (b) has any Non-U.S. Entity with a Direct or Indirect Ownership Interest of 20% or greater; (c) has any combination of Non-U.S. Person(s) and/or Non-U.S.

Entity(-ies) that have an aggregate Direct or Indirect Ownership Interest of greater than or equal to 20%; or (d) may be under Foreign Control, the Recognized Coordinating Entity (RCE) will refer the application to the Office of the National Coordinator for Health Information Technology (ONC) for review to determine whether the Applicant is under Foreign Control.

- 4.3** For purposes of the Means to Demonstrate U.S. Ownership and Control of a QHIN Questionnaire and evaluation of Section 4.1(ii) – (iv) and 4.2 of this SOP, if Applicant is an Entity whose securities are publicly traded on a stock exchange that is regulated by the United States Securities and Exchange Commission, Applicant’s disclosure of Direct or Indirect Ownership of a Non-U.S. Person(s) and/or Non-U.S. Entity(ies) will only be evaluated if such Non-U.S. Person or Non-U.S. Entity holds more than 20% of the Applicant’s securities and has any of the following rights with respect to Applicant:

4.3.1 Power to determine, direct, take, reach, or cause decisions regarding sale, lease, mortgage, pledge, or other transfer of any of the tangible or intangible principal assets of Applicant, whether or not in the ordinary course of business;

4.3.2 Access to or ability to control policies or procedures regarding any material nonpublic technical information in the possession of the Applicant;

4.3.3 Membership or observer rights on, or the right to nominate, appoint, or elect an individual to a position on the board of directors or equivalent governing body of the Applicant;

4.3.4 Appointment, removal or dismissal of officers or senior managers or, in the case of a partnership, the general partner of the Applicant;

4.3.5 Any involvement, other than through voting of shares, in substantive decision-making of the Applicant regarding:

4.3.5.1 The use, development, acquisition, security, safekeeping or release of TEFC A Information (TI);

4.3.5.2 The use, development, acquisition, security or release of critical technologies used by the Applicant in connection with its Connectivity Services; or

4.3.6 Power to direct the management or operations of the Applicant’s Designated Network or otherwise decide matters materially affecting the management or operations of the Applicant in a manner which may impact the Applicant’s ability to function as a QHIN including, but not limited to, appointment or dismissal of employees with access to critical technologies used by the Applicant in connection with its Connectivity Services or the entry into, termination, or non-fulfillment of significant contracts related to Connectivity Services.

- 4.4 For purposes of the Means To Demonstrate U.S. Ownership and Control of a QHIN Questionnaire and evaluation of Section 4.1(ii) – (iv) and 4.2 of this SOP, the ownership of an Applicant’s Participants, Subparticipants, and Downstream Subparticipants will not be considered by the RCE, ONC, or U.S. Department of Health and Human Services Office of National Security (ONS) provided that all Participants, Subparticipants, and Downstream Subparticipants are U.S. Entities.

5 PROCEDURE

1. Applicant will submit the Means To Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire to the RCE with the initial application to be Designated as a QHIN and, if Designated as a QHIN, on an annual basis thereafter.
2. If the answers to the Means To Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire indicate that any of the automatic disqualification scenarios in Section 4.1 of this SOP are present, the Applicant’s application will be denied.
3. If the answers to the Means To Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire indicate that Applicant has any Non-U.S. Person(s) or Non-U.S. Entity(-ies) that have a Direct or Indirect Ownership of 20% or more, individually or in the aggregate, but such Ownership does not result in automatic disqualification, or the Applicant may be under Foreign Control, the RCE will refer the application to ONC, which will refer the application to the ONS for review. If information available to ONS supports a determination of Foreign Control, ONS will notify ONC. The RCE will deny an application if ONS notifies ONC that it has assessed that the Applicant is under Foreign Control.
4. A QHIN must provide advance written notice to the RCE of any change in its responses to the Means To Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire. Such notice must be provided at least thirty (30) days prior to the effective date of the change. There may be limited situations in which a QHIN might not have advance notice of a change in Foreign Control such as, for example only, a sudden change in the composition of the QHIN's governing body. In these *limited* situations, a QHIN must provide written notice to the RCE as soon as possible but no later than five (5) business days after a change in the responses to the Means To Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire. The notice required by this section must be accompanied by an updated Means To Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire.
5. For the avoidance of doubt, a QHIN shall be immediately terminated if any change in the responses to the Means To Demonstrate U.S. Ownership and Control of a QHIN SOP Questionnaire indicate one of the automatic disqualification scenarios in Section 4 of this SOP.

6 EXAMPLES

The following are provided as examples of the ways in which the ownership and control will be evaluated.

1. The Applicant is a U.S. Entity. It is owned 50% by Company A, 25% by Company B and 25% by Company C, all of which are U.S. Entities. Company C is owned 5% by Company D, a Non-U.S. Entity, and 95% by Company E, a U.S. Entity. A Non-U.S. Entity has a 1.25% Indirect Ownership Interest in the Applicant; therefore, the Applicant is not disqualified from being a Designated as a QHIN, and a referral to ONC for review is not required.
2. The Applicant is a U.S. Entity. It is owned 50% by Company A, 25% by Company B and 25% by Company C, all of which are U.S. Entities. Company C is owned 5% by a Non-U.S. Person, and 95% by Company E, a U.S. Entity. A Non-U.S. Person has a 1.25% Indirect Ownership Interest in the Applicant. The Non-U.S. Person is not a director or officer. The Applicant is not disqualified from being a Designated as a QHIN, and a referral to ONC for review is not required.
3. The Applicant is a U.S. Entity. It is owned 51% by Person A, 24% by Company B and 25% by Company C. Person A is a Non-U.S. Person who is a citizen of a non-Five Eyes country, and Company B and C are both U.S. Entities. Person A is not an officer or director nor is the individual an SDN, from an OFAC country or on the OIG exclusion list. Because Person A has more than 50% Ownership Interest in the Applicant and is not a citizen of a Five Eyes Country other than the United States, the Applicant is automatically disqualified.
4. The Applicant is a U.S. Entity. It is owned 51% by Company A, 24% by Company B and 25% by Company C. Company A is a Non-U.S. Entity formed under the laws of Australia, and Company B and C are both U.S. Entities. Because Company A is formed under the laws of a Five Eyes Country other than the United States, the RCE will refer Applicant to ONC for review.
5. The Applicant is a U.S. Entity. It is owned 50% by Company A, 25% by Company B and 25% by Company C, all of which are U.S. Entities. Each of Company A, B and C are owned by U.S. Qualified Person (s). The CEO of the Applicant is a Non-U.S. Person. Because the CEO is a Non-U.S. Person, the RCE will refer the Applicant to ONC for review.
6. The Applicant is a U.S. Entity. It is owned 50% by Company A, 25% by Company B and 25% by Company C, all of which are U.S. Entities. Each of Company A, B, and C are owned by U.S. Qualified Persons. Of the Applicant's five directors, three are Non-U.S. Persons. Because there are directors who are Non-U.S. Persons, the RCE will refer the Applicant to ONC for review.

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