ONC TEFCA RECOGNIZED COORDINATING ENTITY

Standard Operating Procedure (SOP): Means to Demonstrate U.S. Ownership and Control of a QHIN

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

1 Common Agreement References

CA 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 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 Department of Health and Human Services, Office of Inspector General's List of Excluded Individuals/Entities.

CA 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 are 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 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. Individual(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 Cybersecurity and Infrastructure Security Agency, which is a part of the Department of Homeland Security. QHINs are required to protect the privacy and security of TEFCA Information and to support the exchange of TEFCA Information 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 TEFCA Information.

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.

"Foreign Control" means a Non-U.S. Individual(s) or Non-U.S. Entity(ies) has (have) the power, direct or indirect, whether or not exercised, and whether or not exercisable, to direct or decide matters affecting the management or operations of the Applicant in a manner which may impact the Applicant's ability to function as a QHIN.

"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. Individual" 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.

"Person" means mean an individual or Entity.

"U.S. Qualified Individual" 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 U.S. at birth as defined in 8 USC 1408, and lawful permanent residents of the U.S. as defined in Immigration and Nationality Act.

4 Standard

An Entity seeking to be Designated as a QHIN (the "Applicant") will be considered to be owned or controlled by any Non-U.S. Individual(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 an 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 Entity with a Direct or Indirect Ownership Interest in the Applicant of 5% or greater is a Non-U.S. Entity.

(iii) If any combination of Non-U.S. Individuals or Non-U.S. Entity(ies) has (have) an aggregate Direct or Indirect Ownership Interest of 50% or greater in the Applicant.

If the Applicant is not subject to automatic disqualification pursuant to the above criteria and has any combination of Non-U.S. Individual(s) and/or Non-U.S. Entity(-ies) that has (have) a Direct or Indirect Ownership of 5% or more, individually or in the aggregate, or that may be under Foreign Control, the RCE will refer the application to ONC for joint review on a case-by-case basis to determine whether the Applicant is owned by a Non-U.S. Individual(s) or Non-U.S. Entity(-ies) or is under Foreign Control.

5 Procedure

1. Applicant will submit the Foreign Ownership 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 Foreign Ownership Questionnaire indicate that any of the automatic disqualification scenarios in Section 4 of this SOP are present, the Applicant's application will be denied.
3. If the answers to the Foreign Ownership Questionnaire indicate that Applicant has any Non-U.S. Individual(s) or Non-U.S. Entity(-ies) that has (have) a Direct or Indirect Ownership of 5% or more, individually or in the aggregate, but such Ownership does not result in automatic disqualification, or may be under Foreign Control, the RCE will refer the application to ONC for joint review on a case-by-case basis. If ONC and the RCE collectively determine that the Applicant is owned by any Non-U.S. Individual(s) or Non-U.S. Entity(-ies) or under Foreign Control, the Applicant's application will be denied.
4. A QHIN must provide reasonable advance written notice to the RCE of any change in its responses to the Foreign Ownership 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 business days after a change in the responses to the Foreign Ownership Questionnaire. The notice required by this section must be accompanied by an updated Foreign Ownership Questionnaire.
5. For the avoidance of doubt, a QHIN shall be immediately terminated if any change in the responses to the Foreign Ownership Questionnaire indicate one of the automatic disqualification scenarios in Section 4 of this SOP.

6 Examples

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 joint 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. Individual, and 95% by Company E, a U.S. Entity. A Non-U.S. Individual has a 1.25% Indirect Ownership Interest in the Applicant. The Non-U.S. Individual is not a director or officer. The Applicant is not disqualified from being a Designated as a QHIN and a referral to ONC for joint review is not required.

3. The Applicant is a U.S. Entity. It is owned 51% by Individual A, 24% by Company B, and 25% by Company C. Individual A is a Non-U.S. Individual and Company B and C are both U.S. Entities. Individual A is not an officer or director nor is the individual an SDN, from an OFAC country or on the OIG exclusion list. Since Individual A has more than 50% Ownership Interest in the Applicant, the Applicant is automatically disqualified.

4. 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 Individuals. The CEO of the Applicant is a Non-U.S. Individual. Since the CEO is a Non-U.S. Individual, the RCE will refer the Applicant to ONC for joint 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 Individuals. Of the Applicant's five directors, three are Non-U.S. Individuals. Since there are directors who are Non-U.S. Individuals, the RCE will refer the Applicant to ONC for joint review.

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