Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimates for the recordkeeping burden and the reporting burden are based on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years.

Dated: January 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00863 Filed 1–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting to be held on Thursday, February 10, 2022, and Friday, February 11, 2022. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Thursday, February 10, 2022, from 10:00 a.m.–3:00 p.m. Eastern Time (ET) and Friday, February 11, 2022, from 10 a.m.–2:30 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* The deadline for registration is 12:00 p.m. ET on February 9, 2022. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel (RUSP), following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the February 10–11, 2022 meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) Final evidence-based review report on the Mucopolysaccharidosis type II (MPS II) condition nomination for possible inclusion on the RUSP. Following this report, the ACHDNC expects to vote on whether to recommend to the Secretary adding MPS II to the RUSP.

(2) A presentation on phase two of the evidence-based review for Guanidinoacetate methyltransferase (GAMT) deficiency.

(3) An update on the Krabbe disease condition nomination.

(4) A possible vote on whether to move Krabbe disease forward to full evidence-based review.

(5) Overview of ACHDNC consumer-friendly resources.

(6) A presentation on healthy equity in newborn screening.

The agenda for this meeting includes a potential vote which may lead to a decision to recommend a nominated condition (MPS II) to the RUSP. As noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (Krabbe disease) to full evidence-based review, and will hear presentations on the evidence-based review for Guanidinoacetate methyltransferase deficiency, any of which may lead to a recommendation to add or not add a condition/conditions to the RUSP at a future time.

Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website listed above.

Members of the public also will have the opportunity to provide comments. Public participants providing oral comments may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Subject to change: Members of the public registered to submit oral public comments on MPS II are tentatively scheduled to provide their statements on Thursday, February 10, 2022. Members of the public registered to provide statements on all other newborn screening related topics are tentatively scheduled for Friday, February 11, 2022. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Friday, February 4, 2022.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–00896 Filed 1–18–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Publication of the Trusted Exchange Framework and Common Agreement

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice fulfills an obligation under the Public Health Service Act (PHSA), which requires the

National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public internet website, and in the **Federal Register**, the trusted exchange framework and common agreement developed under the PHSA.

FOR FURTHER INFORMATION CONTACT: Michael L. Lipinski, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION: This notice fulfills the obligation under section 3001(c)(9)(C) of the Public Health Service Act (PHSA) to publish the trusted exchange framework and common agreement (TEFCA), developed under section 3001(c)(9)(B) of the PHSA (42 U.S.C. 300jj–11(c)(9)(B)), in the **Federal Register**. The TEFCA consists of the following two documents:

BILLING CODE 4150–45–P

The Trusted Exchange Framework (TEF): Principles for Trusted Exchange

January 2022

This document was published by the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology and was produced at U.S. taxpayer expense.

This document meets the requirement in section 3001(c)(9)(C) of the Public Health Service Act for the National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public Internet website, and in the Federal Register, the trusted exchange framework (42 U.S.C. 300jj-11(c)(9)(C)).

The Office of the National Coordinator for
Health Information Technology

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The Office of the National Coordinator for
Health Information Technology

Overview and Background

The 21st Century Cures Act[1] (Cures Act) directs the National Coordinator to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally." In January 2018, the Office of the National Coordinator for Health Information Technology (ONC) released the first draft of the Trusted Exchange Framework[2] (TEF Draft 1) for public comment. The TEF Draft 1 included two parts: "Part A — Principles for Trusted Exchange," and "Part B — Minimum Required Terms and Conditions for Trusted Exchange." In April of 2019, ONC released the second draft of the TEF (TEF Draft 2) for public comment, which also included "Part A — Principles for Trusted Exchange" and "Part B — Minimum Required Terms and Conditions for Trusted Exchange."

This document represents the final version of the Trusted Exchange Framework (TEF), titled "The Trusted Exchange Framework: Principles for Trusted Exchange." The policies formerly known as the Minimum Required Terms and Conditions (MRTCs) and the Additional Required Terms and Conditions (ARTCs) are now combined into the Common Agreement. The Common Agreement may be viewed in the Federal Register, on ONC's website, and on the website of The Sequoia Project, Inc., the current entity selected through a competitive process by ONC to serve as the Recognized Coordination Entity (RCE) under a cooperative agreement.[3]

The TEF describes a common set of non-binding, foundational principles for trust policies and practices that can help facilitate exchange among health information networks (HINs). Broad industry alignment with these principles should help facilitate entities' entering into effective contractual relationships for the secure electronic flow of digital health information where and when it is needed. The TEF principles also support the ability of patients (or their legal representatives, which may include caregivers), their health care providers, and other authorized health care stakeholders to electronically access digital health information when and where it is needed most to improve care coordination and quality improvement.

The TEF is built on policy principles that have underpinned ONC's activities and federal health IT policies for over a decade. HINs already follow many of these principles. The inclusion of these principles in the TEF provides a means to further advance their use.

[1] Pub. L. 114–255 (Dec. 13, 2016).
[2] https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf.
[3] https://www.healthit.gov/sites/default/files/page/2019-04/TEFCANOFO%20.pdf.

The Office of the National Coordinator for Health Information Technology

Principles for Trusted Exchange

Principle 1 — Standardization: HINs should prioritize federally recognized and industry recognized technical standards, policies, best practices, and procedures.

A. HINs should prioritize health information technology standards for interoperability that the U.S. Department of Health & Human Services (HHS) has adopted in regulations, ONC has identified in the Interoperability Standards Advisory (ISA), or a standards developing organization (SDO) accredited by the American National Standards Institute (ANSI) has published.

Even where a statute or regulation does not require it, trusted exchange efforts should adhere to federally adopted health information technology standards for interoperability to support robust and widespread adoption. HINs should first look to use standards adopted by HHS for use in Health Insurance Portability and Accountability Act (HIPAA) transactions[4] or use in the ONC Health IT Certification Program[5] (Certification Program), including any updated versions of such adopted standards that ONC has approved for use in the Certification Program through the Standards Version Advancement Process (SVAP),[6] and then those identified in the ISA.[7]

In instances where none of the above references include applicable standards, HINs should then consider voluntary consensus or industry standards that are readily available to all stakeholders and published by SDOs accredited by ANSI. Consistent adherence to standards in the manner described in this paragraph will support improved usability and electronic access to digital health information.

B. HINs should implement technology in a manner that makes it easy to use and allows authorized users to connect to data sources, innovate, and use data to support better, more person-centered care, smarter spending, and healthier people.

HINs should use standards-based technology to electronically exchange digital health information within their own HINs and with other HINs. To minimize variation in how standards are implemented, such technology should be implemented in accordance with authoritative implementation specifications and

[4] The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Patient Protection and Affordable Care Act administrative simplification of electronic data interchange provisions are implemented by HHS through the National Standards Group at the Centers for Medicare and Medicaid Services (CMS), which adopts certain transaction standards that are required to be used when electronic data are exchanged in support of covered administrative transactions. These transactions include: health care claims or equivalent encounter information; eligibility for a health plan; enrollment and disenrollment in a health plan; health care electronic funds transfers (EFT) and remittance advice; referral certification and authorizations; health care claims status; coordination of benefits; health plan premium payments; and Medicaid pharmacy subrogation. HIPAA covered entities must use the adopted standards, generally either an ASC X12N or NCPDP standard (for certain pharmacy transactions), in conducting transactions.

[5] *https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program*.

[6] ONC Standards Version Advancement Process, *available at* *https://www.healthit.gov/topic/standards-version-advancement-process-svap*.

[7] ONC Interoperability Standards Advisory (ISA), *available at* https://www.healthit.gov/isa/.

best practices published by an applicable SDO. By doing so, HINs should be better able to connect to each other and with their participants.

HINs should, to the extent possible, ensure that the data exchanged within their own network and with other HINs meets minimum quality standards by using testing and onboarding programs to verify minimum quality levels. HINs may consider using tools to support this analysis, such as ONC's Consolidated Clinical Document Architecture (C-CDA) Scorecard tool for testing the technical conformance of C-CDAs[8] and ONC's Inferno Program Edition tool[9] for testing Fast Healthcare Interoperability Resources (FHIR®) APIs.

Principle 2 — Openness and Transparency: HINs should conduct activities openly and transparently, wherever possible.

A. HINs should make terms, conditions, and contractual agreements that govern the exchange of digital health information easily and publicly available.

All parties desiring to electronically exchange digital health information through a HIN should know, prior to engaging with a HIN, the responsibilities of being a participant in that HIN, the information privacy and security protections the HIN requires, as well as its data use and disclosure policies. HINs should make these and other terms and conditions for participating in their network easily and publicly available, meaning readily found on their websites.

B. HINs should specify and have all of its participants agree to the uses and disclosures for exchanging digital health information.

Because HINs are often either HIPAA business associates of covered entities or a business associate subcontractor of a business associate, their Business Associate Agreements (BAAs) specify the uses and disclosures for which their HIN may be used to electronically exchange digital health information.[10] While some HINs currently support many of the uses and disclosures specifically addressed in the HIPAA Privacy Rule,[11] others may only support use and disclosure of digital health information for treatment purposes.

When HINs vary in allowable uses and disclosures in their agreements, the full electronic exchange of digital health information between those HINs is limited. Therefore, HINs should, in compliance with applicable law, specify the minimum set of uses and disclosures they support. These uses and disclosures should be specified in a HIN's legal agreement with its participants or included in a contract addendum if the legal agreement is already in place, made open and transparent, consistent with Principle 2.A, and

[8] ONC Consolidated-Clinical Document Architecture (C-CDA) Scorecard, https://site.healthit.gov/home.
[9] ONC Inferno Program Edition, https://inferno.healthit.gov/inferno/.
[10] For information about HIPAA covered entities and business associates, *see* 45 CFR 160.103 and https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html.
[11] The "HIPAA Privacy Rule" refers to the privacy regulations under HIPAA, 45 CFR part 160 and subparts A and E of part 164.

clearly communicated to relevant parties prior to when digital health information[12] is requested or sent between participants and HINs.

C. HINs should publish, keep current, and make publicly available the HIN's privacy practices.

Ensuring that participants of HINs understand the privacy practices of each HIN will help to build trust that digital health information will be protected and will not be used in ways that they do not expect. Consequently, HINs and their participants should subscribe to the following privacy practices:

(a) HINs must comply with all applicable laws and regulations regarding the use and disclosure of digital health information. When consent or authorization is required by federal or state law, HINs should have policies for where consent and/or authorization is enforced within their architecture.
(b) HINs should clearly specify the minimum set of uses and disclosures for exchanging digital health information and, for non-treatment purposes, limit the use of digital health information to the minimum amount required.
(c) HINs should advance the ability of individuals to electronically access their digital health information through HINs' privacy practices.

These privacy practices are critical to effective data exchange. To further promote transparency, HINs should publish and make publicly available a notice written in plain language, similar to ONC's Model Privacy Notice,[13] that describes their privacy practices regarding the access, exchange, use, and disclosure of digital health information.

D. HINs should establish and, where applicable, conduct any dispute resolution processes in an equitable and transparent manner.

It may be necessary to address behavior that violates data sharing agreements among HINs. HINs should ensure that a dispute resolution process for addressing such violations is clearly defined in their respective agreements and subsequently followed. Such dispute resolution processes should be equitable and transparent to all parties, particularly prior to when a data sharing entity signs an agreement with a HIN that binds that entity to such processes.

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[12] The term "digital" when used throughout this document has its plain meaning (i.e., its dictionary definition). *See* Merriam-Webster.com., *https://www.merriam-webster.com/dictionary/digital* (retrieved Jan. 7, 2022). For example, the phrase "digital health information" refers to information that is neither faxed nor is hard copy health information. Furthermore, the phrase "digital health information" is used to deliberately avoid use of specific regulatory terms for specific types of health information.
[13] ONC Model Privacy Notice, *available at www.healthit.gov/sites/default/files/2018modelprivacynotice.pdf*.

Principle 3 — Cooperation and Non-Discrimination: HINs should collaborate with stakeholders across the continuum of care to electronically exchange digital health information, even when a stakeholder may be a business competitor.

HINs should not seek to gain competitive advantage or discriminate against competitors by limiting access to individuals' digital health information, and HINs should not treat digital health information as an asset that can be restricted in order to obtain or maintain a competitive advantage. For example, HINs should not withhold digital health information requested for permitted treatment, payment, or health care operations purposes from health care providers or health plans that are outside of their preferred referral networks or outside of a value-based payment arrangement. They should not establish internal policies and procedures that result in such improper withholding of information. Likewise, HINs should not implement technology in a manner that improperly limits the sharing of digital health information. HINs should not knowingly make misleading statements regarding privacy or security laws or regulations as a pretext for not sharing digital health information. HINs should practice data reciprocity (e.g., have a willingness to share digital health information themselves as opposed to participating in an exchange relationship only for the purpose of receiving digital health information from others). In addition, fees and other costs should be reasonable and should not be used to interfere with access, exchange, use, or disclosure of digital health information within a HIN or between HINs.

HINs should not use contract provisions or proprietary technology implementations to unduly limit connectivity with other HINs—such as by preventing the appropriate flow of digital health information across technological, geographic, or organizational boundaries for health and care, safety, quality measurement, or payment. At the same time, HINs are subject to applicable law, which includes restrictions or policies that interact with such potential limits to connectivity (including the applicable HIPAA Rules[14] and information blocking regulations[15]).

HINs should not use methods that discourage or impede appropriate digital health information exchange with competitors or potential competitors. This includes throttling the speed with which data is exchanged purely for competitive reasons, unnecessarily limiting the data that are exchanged with health care organizations that may be their competitor or a competitor of one of their participants, or requiring unnecessary testing requirements designed to unfairly deter or discourage connections that do not benefit the HIN.

[14] The term "HIPAA Rules" refers to the HIPAA Privacy, Security, and Breach Notification Rules, 45 CFR parts 160 and 164.
[15] *See* 45 CFR part 171.

Principle 4 — Privacy, Security, and Safety: HINs should exchange digital health information in a manner that supports privacy; ensures data confidentiality, integrity, and availability; and promotes patient safety.

A. HINs should ensure that digital health information is exchanged and used in a manner that promotes safe care and wellness, including consistently and accurately matching digital health information to an individual.

Health plans and most health care providers, and their business associates must follow the HIPAA Rules to safeguard health information. However, digital health information is increasingly collected, shared, or used by new types of organizations that are beyond the traditional health care organizations covered by the HIPAA Rules. Privacy and security should be a foundation for all HINs and HIN participants, including those that are not subject to HIPAA.

Ensuring the confidentiality, integrity, and availability of digital health information is paramount to providing safe care and supporting the health and well-being of all individuals and communities. When digital health information is exchanged, a foundational step to safe care and wellness begins with correctly matching the data to an individual so that care is provided to the correct individual based on accurate information. Generally, sophisticated algorithms that use demographic data for matching are the primary method for automatically connecting data to an individual within a HIN. Demographic data quality heavily influences the accuracy and completeness that any given patient matching method can achieve. To support accurate matching, HINs should agree upon and consistently share a core set of demographic data each time digital health information is exchanged. Likewise, participants of HINs should ensure that the core set of demographic data is consistently captured for all individuals to enable exchange in a standard format and to accurately match patient data. Furthermore, HINs and their participants should also work to improve the quality of the demographic data that they hold.[16]

Where possible, standard nomenclatures should be used and exchanged in a data format that is consumable by a receiving system, such as a C-CDA or via FHIR APIs. Further, clinicians should update individuals' digital health information in their health IT systems to ensure that medications, allergies, and problems are up to date prior to exchanging such data with another organization. HINs should utilize testing and onboarding processes for their participants to establish a high level of data quality.

B. Within the context of applicable law, HINs should enforce policies concerning individuals' ability to consent to the access, exchange, or use of their digital health information.

When consent or authorization is required by federal or state law, HINs should have policies addressing how consent and/or authorization is enforced within their architecture. The ability to oversee appropriate electronic capture of an individual's consent or authorization to access, exchange, or use their digital health information will engender trust with other entities seeking to exchange with that network.

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[16] ONC's Patient Demographic Data Quality Framework module is intended to support health systems, large practices, health information exchanges, and payers in improving their patient demographic data quality. *See* https://www.healthit.gov/playbook/pddq-framework/.

Differing state laws affect when HINs must obtain consent or authorization from an individual to access, exchange, or use the individual's digital health information. The Privacy Rule does not require a covered entity or its business associates to obtain an individual's consent or authorization before using or disclosing health information for treatment, payment, and health care operations purposes. While the Privacy Rule generally permits covered health care providers to request consent for those purposes, some federal and state laws may require them to do so before they disclose or exchange an individual's digital health information even for treatment and payment purposes. For example, in the case of records regarding human immunodeficiency virus (HIV), mental health, or genetic testing, state laws may impose a more stringent standard (e.g., requiring consent from the individual) than the Privacy Rule.[17] Thus, HINs should have policies that are sufficiently flexible to address these differing consent and authorization requirements.

Principle 5 — Access: HINs should ensure that individuals and their authorized caregivers have easy access to their digital health information and understand how it has been used or disclosed and HINs should comply with civil rights obligations on accessibility.

A. HINs should not impede or impose any unnecessary barriers to the ability of individuals or their legal representatives to access or direct their digital health information to designated third parties, or to learn how information about them has been accessed or disclosed.

HINs who maintain digital health information should (1) enable individuals, or their legal representatives, to easily and conveniently access their digital health information; (2) enable individuals, or their legal representatives, to direct their digital health information to any recipient they designate; and (3) ensure that individuals, or their legal representatives, have a way to learn how their information is shared and used. This principle is consistent with the Privacy Rule, which generally requires covered entities to provide health information to individuals in the form and format in which they request it, if it is readily producible in that form and format.

The Privacy Rule also requires a covered entity to have a Notice of Privacy Practices available to inform individuals about how health information is used and disclosed by the entity, as well as the individual's rights with respect to their health information.

In accordance with applicable law, HINs should support an individual's decision to access their digital health information through an API-enabled third-party application when the individual has directed the HIN to disclose a copy of that individual's health information to the application.

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[17] Privacy and Security Solutions for Interoperable Health Information Exchange, Report on State Law Requirements for Patient Permissions to Disclose Health Information (Aug. 2009), https://www.healthit.gov/sites/default/files/disclosure-report-1.pdf.

In accordance with federal law, HINs that receive federal funding must ensure accessibility by individuals with disabilities and individuals with limited English proficiency.[18]

B. HINs should not impede or impose any unnecessary barriers to the ability of individuals, or their legal representatives, to learn how their health data has been accessed or disclosed.

It is important for individuals, or their legal representatives, to be able to obtain information about how their digital health information has been accessed, used, and disclosed. As the Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information states in its principle on "Openness and Transparency," "[p]ersons and entities, that participate in a network for the purpose of electronic exchange of individually identifiable health information, should provide reasonable opportunities for individuals to review who has accessed their individually identifiable health information or to whom it has been disclosed, in a readable form and format."[19]

HINs should commit to following this principle and should provide such opportunities to review access histories electronically whenever possible, particularly when an individual makes the request electronically. Providing individuals with transparency on how their data has been accessed, used, and disclosed increases their confidence in the HIN.[20] Again, in accordance with federal law, HINs that receive federal funding must ensure accessibility.

Principle 6 — Equity: HINs should consider the impacts of interoperability on different populations and throughout the lifecycle of the activity.

A. HINs should employ a health equity by design approach and should consider the health equity consequences of policy and technology choices up front.

HINs should adopt standards, policies, and processes that explicitly consider health equity.[21] The COVID-19 pandemic amplified the importance of health equity in health IT. Throughout the pandemic,

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[18] *See, e.g.*, Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d-2000d-7 and its implementing regulation at 45 CFR part 80; Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, and its implementing regulation at 45 CFR part 92; and Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794, and its implementing regulation at 45 CFR part 84.

[19] Office of the National Coordinator for Health Information Technology, Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information, at 7 (Dec. 15, 2008), *available at http://www.healthit.gov/sites/default/files/nationwide-ps-framework-5.pdf*.

[20] *See* Privacy and Security Solutions for Interoperable Health Information Exchange, Report on State Law Requirements for Patient Permissions to Disclose Health Information (Aug. 2009), *https://www.healthit.gov/sites/default/files/disclosure-report-1.pdf*.

[21] Exec. Order No. 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, available at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*. This Executive Order defines equity as "the consistent and systematic fair, just, and impartial treatment of all

public health authorities faced challenges in receiving the granular data needed on specific communities because of inconsistent and heterogeneous data collection and exchange across public health systems. Organizations on the frontline were often unable to get sufficient information needed for decision-making to support a targeted public health response.

A health equity by design approach means that HINs should identify the health equity considerations at the outset of any policy creation, technology development process, or implementation approach, and should include those as core constructs to identify and address health inequities and disparities.

B. HINs should evaluate interoperability efforts, ensure health equity is being achieved, and adjust when it is not.

Evaluation and analysis provide essential evidence to understand how programs work, for whom, and under what circumstances.[22] Building evidence through evaluation and analysis informs decisions in a range of areas, including budget formation, regulatory development, strategic planning, program implementation, and policy construction.[23]

HINs should plan and budget for evaluation of their trusted exchange efforts during all stages of an exchange activity's life cycle. Such evaluation should follow best practices including, for example, the Centers for Disease Control and Prevention Framework for Program Evaluation in Public Health.[24] Additionally, as part of continuous quality improvement activities,[25, 26, 27] HINs should consider the results of such ongoing evaluation and make changes to improve outcomes, including changes in the domain of equity.

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individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders, and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality."

[22] Adapted from HHS Office of the Assistant Secretary for Planning and Evaluation, Evaluation & Evidence, *https://aspe.hhs.gov/evaluation-evidence*.

[23] *Id.*

[24] Centers for Disease Control and Prevention, *Framework for Program Evaluation in Public Health*, Morbidity and Mortality Weekly Report, Vol. 48, No. RR-11 (Sept. 17, 1999), *available at* *https://www.cdc.gov/mmwr/PDF/rr/rr4811.pdf*.

[25] Brian O'Donnell and Vikas Gupta, Continuous Quality Improvement (last updated Apr. 7, 2021), *available at* *https://www.ncbi.nlm.nih.gov/books/NBK559239/*.

[26] Office of the National Coordinator for Health Information Technology, National Learning Consortium, Continuous Quality Improvement (CQI) Strategies to Optimize your Practice, *https://www.healthit.gov/sites/default/files/tools/nlc_continuousqualityimprovementprimer.pdf*.

[27] Agency for Healthcare Research and Quality, Health Literacy Universal Precautions Toolkit, 2nd Edition, Plan-Do-Study-Act (PDSA) Directions and Examples, *available at* *https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html*.

Principle 7 — Public Health: HINs should support public health authorities and population-level use cases to enable the development of a learning health system that improves the health of the population and lowers the cost of care.

A. HINs should enable use cases that advance the mission of public health authorities.

Currently, nationwide networks largely support exchange among health care providers for treatment purposes to the exclusion of other critical use cases such as public health, population health, and research. Whenever possible, and in accordance with applicable law, HINs should support use cases that advance priorities for public health authorities.[28, 29] This includes, for example, electronic case reporting, electronic laboratory reporting, case investigations, syndromic surveillance, immunization reporting, adverse event collection or reporting, product defects, product recalls, and post-marketing surveillance.[30, 31]

B. HINs should advance population-level use cases, including quality improvement and research.

Population-level information is fundamental to providing accountability for health care and to enabling a learning health system. A learning health system is defined as a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice.[32] As a result, patients get higher quality, safer, more efficient care, and health care delivery organizations become better places to work.[33]

In alignment with Principle 3.A., HINs should enable data exchange for quality measurement and improvement activities. Providers and health plans may want to work with a HIN, consistent with applicable law, to share digital health information from their health information technology to a qualified

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[28] A "public health authority" is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. *See* 45 CFR 164.501. Examples of a public health authority include State and local health departments, the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA). Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual's authorization, or for disclosures that are required by other law. *See* 45 CFR 164.502(b). For additional information, *see* https://www.hhs.gov/hipaa/for-professionals/special-topics/public-health/index.html.

[29] Office of the National Coordinator for Health Information Technology, Public Health, https://www.healthit.gov/topic/health-it-health-care-settings/public-health.

[30] Centers for Disease Control and Prevention, Public Health Data Interoperability, https://www.cdc.gov/datainteroperability/index.html.

[31] HHS Office of Civil Rights, Public Health, https://www.hhs.gov/hipaa/for-professionals/special-topics/public-health/index.html.

[32] HHS Agency for Healthcare Research and Quality, About Learning Health Systems (last reviewed May 2019), https://www.ahrq.gov/learning-health-systems/about.html.

[33] *Id.*

clinical data registry (QCDR),[34] a qualified entity (QE),[35] researchers, another HIN, or a health IT developer providing care coordination or quality measurement services. Health plans, including employer-sponsored group health plans, may wish to work with HINs to, where appropriate, obtain information that would better support operations, including using analytics for services such as assessing individuals' risk, population health analysis, and quality and cost analyses.

HINs should support biomedical research activities where appropriate and permitted by law. Under the Cures Act, the Secretary is required to establish a program to evaluate the potential use of real-world evidence to help support the approval of a new indication for drugs and to help to support or satisfy post-approval study requirements.[36] The U.S. Food and Drug Administration uses real-world data and real-world evidence to monitor postmarket safety and adverse events and to make regulatory decisions.[37] To support these and other related use cases, HINs should support biomedical research through their trusted exchange activities, where appropriate. As with all data access supported by HINs, research use cases must always be conducted in accordance with applicable law, guidelines, and ethical principles and considerations.

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[34] A Qualified Clinical Data Registry (QCDR) is a CMS-approved vendor that is in the business of improving health care quality. These organizations may include specialty societies, regional health collaboratives, and large health systems or software vendors working in collaboration with one of these medical entities. *See* *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/A-Brief-Overview-of-Qualified-Clinical-Data-Registries.pdf*.

[35] The CMS Qualified Entity (QE) Program, also known as the Medicare Data Sharing for Performance Measurement Program, enables organizations to receive Medicare claims data under parts A, B, and D for use in evaluating provider performance. Organizations approved as QEs are required to use the Medicare data to produce and publicly disseminate CMS-approved reports on provider performance. *See* *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/QEMedicareData*.

[36] Pub. L. 114-255, section 505F.

[37] U.S. Food and Drug Administration, Real World Evidence (content current as of Sept. 30, 2021), *https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence*.

Common Agreement

COMMON AGREEMENT FOR NATIONWIDE HEALTH INFORMATION INTEROPERABILITY

Version 1

January 2022

This document was published by the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology and was produced at U.S. taxpayer expense.

This document meets the requirement in section 3001(c)(9)(C) of the Public Health Service Act for the National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public Internet website, and in the Federal Register, the common agreement (42 U.S.C. 300jj-11(c)(9)(C)).

The Common Agreement
for Nationwide Health Information Interoperability

This Common Agreement for Nationwide Health Information Interoperability (the "Common Agreement" or "Agreement") is entered into as of the _____ day of _____, _____ (the "Effective Date"), by and between The Sequoia Project, Inc., a Virginia non-stock corporation, acting as the current Recognized Coordinating Entity as defined below (the "RCE") and _____, a _____ ("Signatory"). RCE and Signatory may also be referred to herein individually as a "Party" or collectively as the "Parties."

RECITALS

WHEREAS, Section 4003 of the 21st Century Cures Act directed the U.S. Department of Health and Human Services (HHS) National Coordinator to, "in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally;"

WHEREAS, this Common Agreement (including the documents incorporated herein by reference) is the common agreement developed pursuant to Section 4003 of the 21st Century Cures Act;

WHEREAS, The Sequoia Project has been selected by the Office of the National Coordinator for Health Information Technology (ONC) to serve as the RCE for purposes of developing, implementing, maintaining, and updating this Common Agreement, including the Qualified Health Information Network (QHIN) Technical Framework, as well as managing the activities associated with the designation of interested health information networks (HINs) as QHINs (as defined and set forth in this Common Agreement);

WHEREAS, Signatory wishes to be designated as a QHIN and has completed the application process toward such designation;

WHEREAS, Signatory must, among other conditions set forth in this Common Agreement, agree to be bound by the terms of this Common Agreement before Signatory may

be designated as a QHIN and, upon signing this Common Agreement, Signatory agrees to be so bound as a Signatory and as a QHIN, if so designated, as the case may be;

NOW, THEREFORE, in consideration of the mutual promises set forth herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, mutually agree as set forth below.

AGREEMENT

1. Definitions and Relevant Terminology

1.1 Defined Terms. Capitalized terms used in this Common Agreement shall have the meaning set forth below. Where a definition includes one or more citations to a statute, regulation, or standard, the definition shall be interpreted to refer to such statute, regulation, or standard as may be amended from time-to-time.

Applicable Law: all federal, state, local, or tribal laws and regulations then in effect and applicable to the subject matter herein. For the avoidance of doubt, federal agencies are only subject to federal law.

Business Associate: has the meaning assigned to such term at 45 CFR § 160.103.

Business Associate Agreement (BAA): a contract, agreement, or other arrangement that satisfies the implementation specifications described within 45 CFR § 164.504(e), as applicable.

Common Agreement: unless otherwise expressly indicated, this document, the QHIN Technical Framework (QTF), all Standard Operating Procedures (SOPs), and all other attachments, exhibits, and artifacts incorporated herein by reference.

Confidential Information:

Any information that is designated as Confidential Information by the person or entity that discloses it (a "Discloser"), or that a reasonable person would understand to be of a confidential nature, and is disclosed to another person or entity (a "Recipient") pursuant to this Common Agreement. For the avoidance of doubt, "Confidential Information" does not include electronic protected health information (ePHI), as defined in this Common Agreement, that is subject to a Business Associate Agreement and/or other provisions of this Common Agreement.

Notwithstanding any label to the contrary, "Confidential Information" does **not** include any information that: (i) is or becomes known publicly through no fault of the Recipient; or (ii) is learned by the Recipient from a third party that the Recipient reasonably believes is entitled to disclose it without restriction; or (iii) is already known to the Recipient before receipt from the Discloser, as shown by the Recipient's written records; or (iv) is independently developed by Recipient without the use of or reference to the Discloser's Confidential Information, as shown by the Recipient's written records, and was not subject to confidentiality restrictions prior to receipt of such information from the Discloser; or (v) must be disclosed under operation of law, provided that, to the extent permitted by Applicable Law, the Recipient gives the Discloser reasonable notice to allow the Discloser to object to such redisclosure, and such redisclosure is made to the minimum extent necessary to comply with Applicable Law.

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.

Cooperative Agreement: the Cooperative Agreement NAP-AX-19-001 – Trusted Exchange Framework and Common Agreement by and between Sequoia Project, Inc. and HHS, or, if applicable, a successor agreement between Sequoia Project, Inc. and HHS or a successor agreement between a different Recognized Coordinating Entity and HHS.

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 (i) an Individual and (ii) a QHIN, Participant, or Subparticipant, that arises when the QHIN, Participant, or Subparticipant, as applicable, offers services to the Individual 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.

Discovery: for purposes of determining the date on which a TEFCA Security Incident was discovered, the term Discovery shall be determined consistent with 45 CFR § 164.404(a)(2) as if the TEFCA Security Incident were a breach (as defined in 45 CFR § 164.402) except that this term shall also apply to Non-HIPAA Entities.

Dispute: means (i) a disagreement about any provision of this Common Agreement, including any SOP, the QTF, 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).

Dispute Resolution Process: has the meaning assigned to such term in Section 15.1 of this Common Agreement.

Downstream Subparticipant: a Subparticipant that has entered into a Downstream Subparticipant Agreement to use the services of another Subparticipant (referred to as the "Upstream Subparticipant") to send and/or receive information as described in Section 9 of this Common Agreement.

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"), which enables the Downstream Subparticipant(s) to use the services of the Upstream Subparticipant as described in Section 9 of this Common Agreement to send and/or receive 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 Downstream Subparticipant Agreement as defined herein. Any Subparticipant may enter into a Downstream Subparticipant Agreement.

Electronic Protected Health Information (ePHI): has the meaning assigned to such term at 45 CFR § 160.103.

Exchange Purpose(s): means the reason, as authorized by this Common Agreement including the Exchange Purposes SOP, for a Request, Use, Disclosure, or Response transmitted via QHIN-to-QHIN exchange as one step in the transmission. Authorized Exchange Purposes are: Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, Individual Access Services, and any other purpose authorized as an Exchange Purpose by the Exchange Purposes SOP, each to the extent permitted under Applicable Law, under all applicable provisions of this Common Agreement, and, if applicable, under the implementation SOP for the applicable Exchange Purpose.

Framework Agreement(s): any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.

FTC Rule: the Health Breach Notification Rule promulgated by the Federal Trade Commission set forth at 16 CFR Part 318.

Government 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.

Government Health Care Entity: any agency, instrumentality, or other unit of the federal, state, local, or tribal government to the extent that it provides health care services (e.g., Treatment) to Individuals but only to the extent that it is not acting as a Covered Entity.

Health Care Operations: has the meaning assigned to such term at 45 CFR § 164.501, except that this term shall apply to the applicable activities of a Health Care Provider regardless of whether the Health Care Provider is a Covered Entity.

Health Care Provider: has the meaning assigned to such term in the information blocking regulations at 45 CFR § 171.102 or in the HIPAA Rules at 45 CFR § 160.103.

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.*, and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 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 Part 160 and Part 164, Subpart C.

Individual: one or more of the following:

(i) An individual as defined by 45 CFR 160.103;

(ii) Any other natural person who is the subject of the information being Requested, Used, or Disclosed;

(iii) A person who legally acts on behalf of a person described in paragraphs (i) or (ii) of this definition in making decisions related to health care as a personal representative, in accordance with 45 CFR 164.502(g);

(iv) A person who is a legal representative of and can make health care decisions on behalf of any person described in paragraphs (i) or (ii) of this definition; or

(v) An executor, administrator, or other person having authority to act on behalf of a deceased person described in paragraphs (i) or (ii) 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 (IAS): with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, 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 Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.

Individually Identifiable: refers to information that identifies an Individual or with respect to which there is a reasonable basis to believe that the information could be used to identify an Individual.

Minimum Necessary: refers to the provision in the HIPAA Rules that, under certain circumstances, requires a Covered Entity or a Business Associate to make reasonable efforts when Using or Disclosing PHI or when Requesting PHI from another Covered Entity or Business Associate to limit PHI to the minimum necessary to accomplish the intended purpose of the Use, Disclosure, or Request. See 45 CFR § 164.502(b) and § 164.514(d).

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.

Onboarding: the process Signatory, a Participant, or a Subparticipant must undergo to become a QHIN, Participant, or Subparticipant and operational in the production environment under the Framework Agreement to which it is a party. For Signatory, the Onboarding requirements shall be set forth in the Onboarding & Designation SOP addressing the process toward Designation as a QHIN. For a Participant, the Onboarding requirements shall be set forth in the Participant-QHIN Agreement. For a Subparticipant, the Onboarding requirements shall be set forth in the Subparticipant Agreement or the Downstream Subparticipant Agreement, as applicable.

ONC: the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology.

Organized Health Care Arrangement: has the meaning assigned to such term at 45 CFR § 160.103.

Participant: to the extent permitted by applicable SOP(s), a U.S. Entity 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 information via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes.

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 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, which enables the Subparticipant(s) to use the services of the Participant as described in Section 9 of this Common Agreement to send and/or receive 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 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.

Privacy and Security Notice: has the meaning assigned to such term in Section 10.3 of this Common Agreement.

Protected Health Information (PHI): has the meaning assigned to such term 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 described in Section 5.2 of this Common Agreement and incorporated by reference into this Common Agreement, as may be amended, that may include: (i) technical requirements, functional requirements, and privacy- and security-related requirements for the exchange of TI between QHINs; (ii) internal-QHIN functional requirements; (iii) 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 (iv) operational requirements that enable the exchange of TI between and among QHINs.

Qualified Health Information Network (QHIN): to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity 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 the Common Agreement with QHINs in order to impose, at a minimum, the requirements of the Common Agreement, including the SOPs and the QTF, on the QHINs and administer such requirements on an ongoing basis. The RCE is a Party to this Common Agreement.

Request(s) (including its correlative uses/tenses "Requested" and "Requesting"): the act of asking for information in accordance with the applicable requirements of the Framework Agreements.

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 Signatory must require Participants to obligate Subparticipants 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:

Electronic information maintained by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement:

(i) that would be ePHI if maintained by 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.

Notwithstanding the foregoing, the following types of information are **not** 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).

Response(s) (including its correlative uses/tenses "Responded" and "Responding"): the act of providing information or the information provided in accordance with the applicable requirements of the Framework Agreements.

Signatory: the entity that has satisfied Section 4.1 and is a Party to this Common Agreement.

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. Each SOP identifies the relevant group(s) to which the SOP applies, including whether Participants and/or Subparticipants are required to comply with a given SOP. An SOP shall be deemed in effect when adopted pursuant to Section 5.3 of this Common Agreement and listed on a public website.

Subparticipant: to the extent permitted by applicable SOP(s), a U.S. Entity 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 as described in Section 9 of this Common Agreement to send and/or receive information; or (ii) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used as described in Section 9 of this Common Agreement to send and/or receive information.

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. As a matter of general policy, once TI is received by a QHIN, Participant, or Subparticipant that is a Covered Entity or Business Associate and is incorporated into such recipient's system of records, the information is no longer TI and is governed by the HIPAA Rules and other Applicable Law.

TEFCA Security Incident(s):

(i) An unauthorized acquisition, access, Disclosure, or Use of unencrypted TI in transit using the Connectivity Services or pursuant to any Framework Agreement between Signatory and its Participants, between Signatory's Participants and their Subparticipants, or between Subparticipants, but **NOT** including the following:

(a) 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.

(b) 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 QHIN, Participant, or Subparticipant participates or serves as a Business Associate, 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.

(c) 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.

(d) A Disclosure of TI that has been de-identified in accordance with the standard at 45 CFR § 164.514(a).

(ii) 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 Common Agreement or otherwise adversely affect their participation in QHIN-to-QHIN exchange.

Threat Condition: (i) a breach of a material provision of this Common Agreement that has not been cured within fifteen (15) days of receiving notice of the material breach (or such other period of time to which the Parties have agreed), which notice shall include such specific information about the breach that the RCE has available at the time of the notice; or (ii) a TEFCA Security Incident; or (iii) an event that Signatory, its Participant, or their Subparticipant has reason to believe will disrupt normal exchange under the Framework Agreements, either due to actual compromise of or the need to mitigate demonstrated vulnerabilities in systems or data of the QHIN, Participant, or Subparticipant, as applicable, or could be replicated in the systems, networks, applications, or data of another QHIN, Participant, or Subparticipant.

Treatment: has the meaning assigned to such term at 45 CFR § 164.501.

United States: the 50 States, the District of Columbia, and the territories and possessions of the United States including, without limitation, all military bases or other military installations, embassies, and consulates operated by the United States government.

Unsecured: has the meaning assigned to such term at 45 CFR § 164.402 regarding PHI as if it applied to TI that is Individually Identifiable.

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.

Upstream Subparticipant: a Subparticipant that provides services to a Downstream Subparticipant pursuant to a Downstream Subparticipant Agreement to send and/or receive information as described in Section 9 of this Common Agreement.

Use(s) (including correlative uses/tenses, such as "Uses," "Used," 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.

1.2 Common Agreement Terminology.

1.2.1 References to Signatory and QHINs. As set forth in its definition and in the introductory paragraph of this Common Agreement, the term "Signatory" is used to refer to the specific entity that is a Party to this Common Agreement with the RCE. Any and all rights and obligations of a QHIN stated herein are binding upon Signatory upon signing the Common Agreement and are also binding upon all other QHINs. References herein to "other QHINs," "another QHIN," and similar such terms are used to refer to any and all other organizations that have signed the Common Agreement with the RCE.

1.2.2 References to **"(Required Flow-Down(s))"**. Provisions of this Common Agreement containing Required Flow-Downs are identified in the applicable section/subsection title as "**(Required Flow-Down(s))**." For purposes of

implementing the Required Flow-Downs, references in such sections/subsections to "Signatory" shall be interpreted to also mean "Participant(s)" and "Subparticipant(s)," as the case may be. References to "Common Agreement" shall be interpreted to mean the applicable Framework Agreement, as the case may be.

1.2.3 General Rule of Construction. For the avoidance of doubt, a reference to a specific section of the Common Agreement in a particular section does not mean that other sections of this Common Agreement that expressly apply to a QHIN (or to a Participant or a Subparticipant pursuant to a Required Flow-Down) are inapplicable.

2. **Incorporation of Recitals.** The Recitals set forth above are incorporated into this Common Agreement in their entirety and shall be given full force and effect as if set forth in the body of this Common Agreement.

3. **Governing Approach**

3.1 Role of the RCE and ONC. ONC was directed by Congress in the 21st Century Cures Act to, "in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." ONC entered into the Cooperative Agreement with the RCE to develop, implement, maintain, and update the Common Agreement.

Under the terms and conditions of the Cooperative Agreement, the RCE is responsible for matters related to the development and operation of the exchange of TI and related activities.

ONC provides oversight of the RCE's work under the Cooperative Agreement. Under the Cooperative Agreement, ONC has the right to review the RCE's conduct, including Designation, corrective action, and/or termination decisions regarding QHINs, the proper execution of nondiscrimination and conflict of interest policies that demonstrate a commitment to transparent, fair, and nondiscriminatory treatment by the RCE of QHINs, and whether the RCE has adhered to the

requirements imposed upon it by this Common Agreement. ONC may also address complaints made by a QHIN against the RCE as set forth in Section 15.6.1.

3.2 Participation in Governance. QHINs, Participants, and Subparticipants shall have the opportunity to engage in governance under the Common Agreement.

3.2.1 Role. The Transitional Council and the Governing Council, each as defined below, shall be responsible for the following:

(i) Serving as a resource to the RCE and a forum for orderly and civil discussion of any issues affecting exchange activities or other issues that may arise under the Common Agreement;

(ii) Supporting the RCE in its work to monitor the exchange of TI and other activities under the Common Agreement and serving as a resource to the RCE to identify possible corrective actions for conditions that disrupt exchange activities, including, but not limited to, the following:

(a) Provide advice on issues related to the Onboarding of QHINs;

(b) Assist in evaluating suspected or alleged non-compliance with requirements in this Common Agreement, the SOPs, and the QTF;

(c) Provide input regarding whether to suspend or terminate a QHIN's participation;

(d) Provide advice regarding issues before they become Disputes and are escalated to the formal Dispute Resolution Process; and

(e) Evaluate possible and actual TEFCA Security Incidents, other Threat Conditions, and information and/or recommendations from the Cybersecurity Council.

(iii) Reviewing proposed amendments to the Common Agreement, the QTF, and SOPs and providing feedback to the RCE on the proposed changes;

(iv) Participating in the development of new SOPs and providing feedback to the RCE on the proposed changes;

(v) Participating with the RCE in oversight of the Dispute Resolution Process as set forth in this Common Agreement and the Dispute Resolution Process SOP;

(vi) Informing the RCE on development and updating of the strategic roadmap for exchange activities under the Common Agreement; and

(vii) Advocating for the value of the exchange activities under the Common Agreement and promoting their success.

3.3 Transitional Council. To promote a speedy and efficient ramp-up of the Governing Council, a "Transitional Council" shall serve for a twelve- (12-) month term beginning within thirty (30) days after the RCE announces the first group of QHINs that the RCE Designates. The Transitional Council shall serve as the interim governing body for the activities conducted under the Framework Agreements, as more fully described below and in the Transitional Council SOP.

3.3.1 Transition to the Governing Council:

(i) Transition Plan Development – In addition to the responsibilities listed for participation in governance generally, the Transitional Council shall develop the transition plan to the Governing Council.

(ii) Formation of Caucuses – The RCE shall work with the Transitional Council to form the caucuses described in Section 3.4.1 as part of the transition plan. The caucuses are responsible for identifying individuals to serve on the Governing Council that will be established at the end of the twelve (12) months following the formation of the Transitional Council.

(iii) Transition Timing – At the end of the twelve (12) months following the formation of the Transitional Council, the Governing Council shall assume responsibility for participating in the governance of the exchange and related activities under the Common Agreement with the RCE.

(iv) Continuity – Notwithstanding the twelve- (12-) month term of the Transitional Council, the representatives on the Transitional Council

will continue to serve in their governance role until the representatives of the Governing Council are elected and instated.

3.4 Governing Council. A Governing Council shall be established through election of individual members by each of the caucuses described below by the end of the first twelve (12) months following the date on which the RCE announces the first set of QHINs that it has Designated. The election process and constitution of the Governing Council is more fully set forth in the Governing Council SOP. The Governing Council shall serve as the permanent governing body for activities conducted under the Framework Agreements, as more fully described in the Governing Council SOP.

3.4.1 Caucuses.

(i) QHIN Caucus – Every QHIN shall have the right to appoint one (1) individual who is affiliated with that QHIN, as either an employee or independent contractor, to serve as a member of the QHIN Caucus. The QHIN Caucus will be facilitated by the RCE and shall serve as a forum for QHINs to meet and discuss issues of interest directly related to the exchange of TI and related activities under the Common Agreement.

(ii) Participant/Subparticipant Caucus – Each QHIN shall have the right to appoint up to three (3) individuals who are affiliated with a Participant or a Subparticipant, either as an employee or independent contractor, to serve as a member of the Participant/Subparticipant Caucus. In appointing such individuals, QHINs should consider the composition of their Participants and Subparticipants and should endeavor to select persons who will be representative of the various perspectives of the QHIN's Participant/Subparticipant population. The Participant/Subparticipant Caucus will be facilitated by the RCE and shall provide a forum for Participants to meet and discuss issues of interest directly related to the exchange of TI and related activities under the Common Agreement.

3.5 Advisory Groups. The RCE, in consultation with the Governing Council and ONC, may establish "Advisory Groups," from time to time, for purposes of seeking input from distinct groups of stakeholders that are parties to or affected by activities under the Framework Agreements to better inform the governance process, provide input on certain topics, and promote inclusivity. The process for establishing Advisory Groups and selecting members is set forth in the applicable SOP.

4. QHIN Designation

4.1 Eligibility to be Designated. Signatory affirms that it meets the eligibility criteria listed below and the requirements for demonstrating satisfaction of these criteria that are included in the Onboarding & Designation SOP. Signatory must meet the following criteria at the time Signatory submits an application for Designation:

(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.

(ii) Signatory is able to exchange Required Information, as defined in this Common Agreement. The specific, required means to demonstrate this are set forth in an SOP.

(iii) Signatory must demonstrate that it has the ability to perform all of the required functions of a QHIN in the manner required by this Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE. Signatory can demonstrate this by having been in operation and supporting the query functionality as outlined in the QTF, or other functionally comparable exchange method, for at least the twelve (12) calendar months immediately preceding its application to be Designated. However, the RCE will consider other evidence that Signatory may offer to demonstrate compliance with this eligibility criterion as more fully set forth in the applicable SOP. Notwithstanding the foregoing, if Signatory does not demonstrate that it has been supporting query functionality as outlined in the QTF, the RCE may deem this requirement to be satisfied on an interim basis and Designate Signatory under a provisional status, subject to additional monitoring as further provided in the Onboarding & Designation SOP, including additional review during a provisional period.

(iv) Signatory must demonstrate that it has in place, at the time of its application to be Designated, the organizational infrastructure and legal authority to comply with the obligations of the Common Agreement and a functioning system to govern its Health Information Network. In addition, Signatory must demonstrate it has the resources and infrastructure to support a reliable and trusted network. The specific, required means to demonstrate this are set forth in an SOP.

4.2 Affirmation of Application. Signatory represents and warrants that the information in its application is accurate and complete, to the best of its knowledge. Signatory acknowledges that the RCE is relying upon the information in its application to evaluate whether Signatory meets the criteria to be Designated and that violation of this representation and warranty is a material breach of this Common Agreement. If the RCE determines that material information in the application is not accurate or complete, the RCE may refuse to Designate Signatory and withdraw Signatory from Onboarding and terminate this Common Agreement in accordance with 16.2.2.

4.3 QHIN Designation Process. RCE and Signatory will work cooperatively and diligently to allow Signatory to demonstrate that it meets the QHIN eligibility requirements and can comply with the requirements included in this Common Agreement, the QTF, and the SOPs; however, the burden is upon Signatory to demonstrate that it does comply with such requirements. Signatory expressly acknowledges that the RCE is not required to Designate Signatory in the event that Signatory fails to meet the requirements. Signatory agrees that it will not represent that it is a QHIN unless, and until, the RCE formally Designates Signatory. The detailed process for the RCE to review Signatory's application shall be set out in an SOP.

4.4 Formal Designation as a QHIN. If Signatory demonstrates to the RCE that it meets the requirements to be Designated, and affirms that it is a HIN, then the RCE will inform Signatory of its QHIN Designation. The process for Signatory to be formally Designated shall be set out in an SOP.

5. Change Management

5.1 Change Management Framework. The RCE shall coordinate all changes to the Common Agreement, the QTF, and the SOPs in conjunction with ONC. In addition to the activities described below, ONC shall be available in a consultative role throughout the change management process to review any proposed amendments to the Common Agreement, the QTF, and the SOPs as well the adoption of any new SOP and the repeal of any existing SOP. The RCE will work with ONC, the Governing Council, and the QHIN and Participant/Subparticipant Caucuses, as outlined below, to consider amendments to the Common Agreement, the QTF, or the SOPs and the adoption of any new SOP or the repeal of any existing SOP. Provided, however, that the actions described in Sections 5.1 through 5.3 of this Common Agreement by or with respect to the Governing Council, the QHIN Caucus, and the Participant/Subparticipant Caucus, as applicable, shall not be required until the respective body has been established as described in Section 3. Signatory acknowledges that it and the RCE do not have the sole legal authority to agree to

changes to this Common Agreement, the QTF, or the SOPs because ONC will be available in a consultative role throughout the process and must approve all changes, additions, and deletions. The Common Agreement must be the same for all QHINs.

5.2 Amending the Common Agreement or the QTF. The RCE is tasked, under its Cooperative Agreement with ONC, with developing an initial QTF. The QTF Version 1 will be made publicly available prior to the initial QHIN application period (i.e., prior to *anyone* signing the Common Agreement). Proposed amendments to the Common Agreement or QTF may originate from multiple sources, including, but not limited to, ONC, the RCE, the Governing Council, the QHIN Caucus, or the Participant/Subparticipant Caucus. The RCE shall consider all proposed amendments and determine, in conjunction with ONC, whether further action on a proposed amendment is warranted.

5.2.1 If the RCE determines that a proposed amendment warrants further consideration after consultation with ONC, then the RCE will present the proposed amendment to the Governing Council for its review and consideration. The Governing Council will evaluate the proposed amendment and determine whether it will seek feedback from the QHIN Caucus, the Participant/Subparticipant Caucus, or both, as deemed necessary and appropriate. The Governing Council will provide the RCE with written feedback on the proposed amendment, which will include feedback from the QHIN and Participant/Subparticipant Caucuses as applicable and appropriate.

5.2.2 The RCE shall consult with ONC about the Governing Council feedback and determine whether the proposed amendment should proceed. If the RCE decides to proceed with the amendment, it will publish the proposed amendment to the QHIN Caucus for approval by a written vote. An amendment will be approved if both of the following have occurred: (i) at least two-thirds (2/3) of the votes cast by the QHIN Caucus members within the timeframe established by RCE for the voting period are in favor of the proposed amendment, to ensure each QHIN gets one vote but one vote only; and (ii) ONC approves the amendment in writing after approval by the QHIN Caucus as described in subsection (i) of this 5.2.2. Subsection (i) herein shall be satisfied by the RCE's approval of the proposed amendment if, at the time of such approval, the Governing Council and the QHIN Caucus have not yet been established.

5.2.3 The time period for ONC to approve or disapprove of a proposed amendment to the Common Agreement pursuant to subsection 5.2.2(ii)

above shall initially be three (3) months after ONC receives notice from the RCE that the proposed amendment has been approved pursuant to subsection 5.2.2(i) above; provided, however, that ONC may, in its discretion, extend this time for an unlimited number of additional three- (3-) month time periods.

5.2.4 The time period for ONC to approve or disapprove of a proposed amendment to the QTF pursuant to subsection 5.2.2(ii) above shall initially be three (3) months after ONC receives notice from the RCE that the proposed amendment has been approved pursuant to subsection 5.2.2(i) above; provided, however, that ONC may, in its discretion, extend this time for one (1) additional three- (3-) month time period.

5.2.5 If an amendment to the Common Agreement or QTF is approved as described above, the amendment shall become effective on the effective date identified by the RCE as part of the amendment process and shall be binding on Signatory without any further action by Signatory or the RCE. If Signatory is not willing or able to comply with the amendment, then Signatory shall, within fifteen (15) business days of being notified by the RCE that the amendment has been approved by ONC, provide the RCE written notice of termination of this Common Agreement effective no later than the expiration of thirty (30) days from approval of the amendment.

5.2.6 Notwithstanding the foregoing, if the RCE determines, based on advice from legal counsel, that an amendment to the Common Agreement or QTF is required in order for the RCE to remain in compliance with Applicable Law, the RCE is not required to provide QHINs with an opportunity to vote on the amendment. However, the RCE shall still be required to provide sixty (60) days' advance written notice of the amendment and the legal analysis of the need to use this expedited process, unless the RCE would be materially harmed by being out of compliance with Applicable Law if it provided the sixty (60) days' written notice, in which case it will provide as much notice as practicable under the circumstances. Any such amendment to this Common Agreement or the QTF shall be subject to ONC review prior to enactment. Only those amendments that are approved by ONC will be enacted.

5.3 Amending, Adopting, or Repealing an SOP. The RCE is tasked, under its Cooperative Agreement with ONC, with developing an initial set of SOPs that will be considered adopted when initially made publicly available prior to the initial QHIN application period (i.e., prior to *anyone* signing the Common Agreement). The "amendment" process set forth below shall also apply to amending the initial set of SOPs through

adopting one or more new SOPs, repealing an SOP in its entirety, or amending one of the initial SOPs.

5.3.1 Proposed amendments to the SOPs may originate from multiple sources including, but not limited to, ONC, the RCE, the Governing Council, the QHIN Caucus, or the Participant/Subparticipant Caucus. The RCE shall consider all proposed amendments and determine, in consultation with ONC, whether further action on a proposed amendment is warranted.

5.3.2 If the RCE determines that a proposed amendment warrants further consideration after consultation with ONC, then the RCE will present the proposed amendment to the Governing Council for its review and consideration. The Governing Council will evaluate the proposed amendment and determine whether it will seek feedback from the QHIN Caucus, the Participant/Subparticipant Caucus, or both, as deemed necessary and appropriate. The Governing Council will evaluate proposed amendments in a timely manner and provide the RCE with written feedback on the proposed amendment.

5.3.3 The RCE shall consult with ONC about the Governing Council feedback and determine whether the proposed amendment should proceed. If the RCE decides to proceed with the amendment, it will publish the proposed amendment to the QHIN Caucus and the Participant/Subparticipant Caucus for approval by a written vote. An amendment will be approved if both of the following have occurred: (i) at least two-thirds (2/3) of the votes cast by the QHIN Caucus and at least two-thirds (2/3) of the votes cast by the Participant/Subparticipant Caucus within the timeframe established by RCE for the voting period are in favor of the proposed amendment; and (ii) ONC approves the amendment in writing after approval by the QHIN Caucus and the Participant/Subparticipant Caucus as described in subsection (i) of this 5.3.3. Subsection (i) herein shall be satisfied by the RCE's approval of the proposed amendment if, at the time of such approval, the QHIN Caucus and the Participant/Subparticipant Caucus have not yet been established.

5.3.4 The time period for ONC to approve or disapprove of a proposed amendment to an SOP pursuant to subsection 5.3.3(ii) above shall initially be three (3) months after ONC receives notice from the RCE that it has been approved pursuant to subsection 5.3.3(i) above or subsection 5.3.5(i) below; provided, however, that: (a) ONC may, in its discretion, extend this time for one (1) additional three- (3-) month time period; and (b) if ONC, in addition, determines in its reasonable discretion that the amendment affects or may

be contrary to an ONC required policy or another policy of the Department of Health and Human Services or any Applicable Law, ONC may extend this time for an unlimited number of additional three- (3-) month time periods.

5.3.5 Notwithstanding the process set forth in 5.3.3(i), if the proposed amendment will not have a material impact on any Participants or Subparticipants, the RCE may publish the proposed amendment to the QHIN Caucus only, whereby the amendment will be approved if both of the following have occurred: (i) at least two-thirds (2/3) of the votes cast by the QHIN Caucus within the timeframe established by RCE for the voting period are in favor of the proposed amendment; and (ii) ONC approves the amendment in writing after approval by the QHIN Caucus as described in subsection (i) of this 5.3.5. Subsection (i) herein shall be satisfied by the RCE's approval of the proposed amendment if, at the time of such approval, the QHIN Caucus has not yet been established. The RCE will determine an effective date for the approved amendment subject to approval of ONC.

5.3.6 Notwithstanding the foregoing, if the RCE determines, based on advice from legal counsel, that an amendment to an SOP is required in order for the RCE to remain in compliance with Applicable Law, the RCE is not required to provide the QHIN Caucus or the Participant/Subparticipant Caucus with an opportunity to vote on the amendment. However, the RCE shall still be required to provide sixty (60) days' advance written notice of the amendment and the legal analysis of the need to use this expedited process, unless the RCE would be materially harmed by being out of compliance with Applicable Law if it provided the sixty (60) days' written notice, in which case the RCE will provide as much notice as practicable under the circumstances. Any such amendment to an SOP shall be subject to ONC review prior to enactment. Only those amendments that are approved by ONC will be enacted.

5.4 Voting Method. For purposes of the voting process set forth in this Section 5, the phrase "written vote" includes any process by which there is a voting record, which may include voting by electronic means.

6. Cooperation and Non-Discrimination

6.1 Cooperation **(Required Flow-Down)**. Signatory understands and acknowledges that numerous activities with respect to this Common Agreement will likely involve other QHINs and their respective Participants and Subparticipants, as well as employees,

agents, third-party contractors, vendors, or consultants of each of them. To the extent not in violation of Applicable Law, Signatory shall, and shall also require that its Participants and their Subparticipants incorporate the following obligations into all Framework Agreements to which they are a party, if any:

(i) Respond in a timely manner, as may be further provided in an SOP, to inquiries from the RCE or other QHINs about possible issues related to their exchange of information under the Common Agreement;

(ii) Participate collaboratively in discussions coordinated by the RCE to address differing interpretations of requirements in this Common Agreement, the QTF, or any SOP prior to pursuing the Dispute Resolution Process;

(iii) Make reasonable efforts to notify the RCE and other QHINs, as appropriate, when persistent and widespread connectivity failures are occurring with Signatory or its Participants or their Subparticipants, so that all those affected can investigate the problems and identify the root cause(s) of the connectivity failures;

(iv) Work cooperatively, including, without limitation, facilitating contact between other QHINs or their Participants or their Subparticipants and Signatory's Participants or their Subparticipants, to address the root cause(s) of persistent and widespread connectivity failures;

(v) Provide information (or require its Participants to provide information or to require their Subparticipants to do so) to other QHINs in support of collaborative efforts to resolve issues or Disputes, provided that such information is subject to Signatory's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges in any reasonably foreseeable litigation or protecting Confidential Information;

(vi) Provide information to aid the efforts of other QHINs or their respective Participants or Subparticipants to understand, contain, and mitigate a TEFCA Security Incident at the request of such other QHINs or their respective Participants or Subparticipants, provided that such information is subject to Signatory's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges in any reasonably foreseeable litigation or protecting Confidential Information; and

(vii) Subject to Signatory's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges in any reasonably foreseeable litigation or protecting Confidential Information, disclose to the RCE information that Signatory, or its Participants or their Subparticipants, may have that relates to the following:

(a) cybersecurity risk information sharing programs; or

(b) specific, identified security flaws in the operation of the QHIN or its Participants or their Subparticipants that may require the QHIN or its Participants or their Subparticipants to take specific steps to protect the security of their information technology systems and would not otherwise fall into subsection (a).

In no case shall Signatory be required to disclose TI or other information in violation of Applicable Law. In seeking cooperation, Signatory shall make all reasonable efforts to accommodate the other QHIN's(') schedules and reasonable operational concerns. The costs of cooperation to Signatory shall be borne by Signatory and shall not be charged to the RCE or other QHINs. Nothing in this Section 6.1 shall modify or replace the TEFCA Security Incident notification obligations under Section 12.3 and, if applicable, Section 10.5.3 of this Common Agreement.

6.2 Non-Discrimination.

6.2.1 Prohibition Against Exclusivity **(Required Flow-Down)**. Neither Signatory nor the RCE shall prohibit or attempt to prohibit any QHIN, Participant, or Subparticipant from joining, exchanging with, conducting other transactions with, or supporting any other networks or exchange frameworks, using services *other than* the Connectivity Services, concurrently with the QHIN's, Participant's, or Subparticipant's participation in exchange activities conducted under the Framework Agreements.

6.2.2 No Discriminatory Limits on Exchange of TI **(Required Flow-Down)**. Signatory shall not impede the exchange of information as permitted or required under the applicable Framework Agreements or limit interoperability with any other QHIN, Participant, Subparticipant, or Individual in a discriminatory manner. As used in this Section 6.2.2, a "discriminatory manner" means

action that is inconsistently taken or not taken with respect to any similarly situated QHIN, Participant, Subparticipant, Individual, or group of them, whether it is a competitor, or whether it is affiliated with or has a contractual relationship with any other entity, or in response to an event. Notwithstanding the foregoing, limitations, load balancing of network traffic, or other activities, protocols, or rules shall not be deemed discriminatory to the extent that they: (i) satisfy the requirements of the exception set forth in 45 CFR 171.205; and/or (ii) are based on a reasonable and good-faith belief that the other entity or group has not satisfied or will not be able to satisfy the applicable terms hereof (including compliance with Applicable Law) in any material respect, including, if applicable, any Required Flow-Down(s). One QHIN suspending its exchange activities with another QHIN in accordance with Section 16.4.2 shall not be deemed discriminatory.

6.2.3 Updates to Connectivity Services. In revising and updating its Connectivity Services from time to time, Signatory will use commercially reasonable efforts to do so in accordance with generally accepted industry practices and implemented in a non-discriminatory manner; provided, however, this provision shall not apply to limit modifications or updates to the extent that such revisions or updates are required by Applicable Law or implemented to respond promptly to newly discovered privacy or security threats.

6.2.4 Notice of Updates to Connectivity Services. Signatory shall implement a reporting protocol to provide reasonable prior written notice of all modifications or updates of its Connectivity Services to all other QHINs if such revisions or updates are expected to adversely affect the exchange of TI between QHINs or require changes in the Connectivity Services of any other QHIN, regardless whether they are necessary due to Applicable Law or newly discovered privacy or security threats.

7. Confidentiality and Accountability

7.1 Confidential Information **(Required Flow-Down)**. Signatory and RCE each agree to use all Confidential Information received pursuant to this Common Agreement only as authorized in this Common Agreement and any applicable SOP(s) and solely for the purposes of performing its obligations under this Common Agreement or the proper exchange of information under the Common Agreement and for no other purpose. Each Party may act as a Discloser and a Recipient, accordingly. A Recipient will disclose the Confidential Information it receives only to its employees, subcontractors, and agents who require such knowledge and use in the ordinary

course and scope of their employment or retention and are obligated to protect the confidentiality of the Discloser's Confidential Information in a manner substantially equivalent to the terms required herein for the treatment of Confidential Information. Otherwise, a Recipient agrees not to disclose the Confidential Information received to anyone except as permitted under this Common Agreement.

7.2 QHIN Accountability.

7.2.1 Statement of General Principle. To the extent not prohibited by Applicable Law, Signatory shall be responsible for its acts and omissions, and the acts or omissions of its Participants and their Subparticipants, but not for the acts or omissions of any other QHINs or their Participants or Subparticipants. **For the avoidance of doubt, a Signatory that is also a governmental agency or instrumentality shall not be liable to the extent that the Applicable Law that governs Signatory does not expressly waive Signatory's sovereign immunity.** Notwithstanding any provision in this Common Agreement to the contrary, Signatory shall not be liable for any act or omission if a cause of action for such act or omission is otherwise prohibited by Applicable Law. This section shall not be construed as a hold-harmless or indemnification provision.

7.2.2 Harm to RCE. Subject to Sections 7.3 and 7.4 of this Common Agreement that exclude certain types of damages or limit overall damages, Signatory shall be responsible for harm suffered by the RCE to the extent that the harm was caused by Signatory's breach of this Common Agreement and/or any applicable SOP.

7.2.3 Harm to Other QHINs. Subject to Section 7.4 of this Common Agreement, which excludes certain types of damages or limits overall damages, Signatory shall be responsible for harm suffered by another QHIN to the extent that the harm was caused by Signatory's breach of this Common Agreement and/or any applicable SOP.

7.3 RCE Accountability. Signatory will not hold the RCE, or anyone acting on its behalf, including but not limited to members of the Governing Council, Transitional Council, Caucuses, Cybersecurity Council, and any Advisory Group, work group, or subcommittee, its contractors, employees, or agents liable for any damages, losses, liabilities, or injuries arising from or related to this Common Agreement, except to the extent that such damages, losses, liabilities, or injuries are the direct result of

the RCE's breach of this Common Agreement. This section shall not be construed as a hold-harmless or indemnification provision.

7.4 **LIMITATION ON LIABILITY. NOTWITHSTANDING ANYTHING IN THIS COMMON AGREEMENT TO THE CONTRARY, IN NO EVENT SHALL EITHER THE RCE'S OR SIGNATORY'S TOTAL LIABILITY TO EACH OTHER AND ALL OTHER QHINS ARISING FROM OR RELATING TO THIS COMMON AGREEMENT EXCEED AMOUNTS EQUAL TO TWO MILLION DOLLARS ($2,000,000) PER INCIDENT AND FIVE MILLION DOLLARS ($5,000,000) AGGREGATE PER ANNUM OR SUCH OTHER AMOUNTS AS STATED IN A THEN-IN-EFFECT SOP, IN ORDER TO ALLOW FOR THE PERIODIC ADJUSTMENT OF THIS LIABILITY LIMIT OVER TIME WITHOUT THE NEED TO AMEND THIS COMMON AGREEMENT. THIS AND ANY SUCH ADJUSTED LIMITATION ON LIABILITY SHALL APPLY REGARDLESS OF WHETHER A CLAIM FOR ANY SUCH LIABILITY OR DAMAGES IS PREMISED UPON BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY, OR ANY OTHER THEORIES OF LIABILITY, EVEN IF SUCH PARTY HAS BEEN APPRISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OCCURRING. IF SIGNATORY IS A GOVERNMENT AGENCY OR A GOVERNMENT INSTRUMENTALITY UNDER FEDERAL LAW, STATE LAW, LOCAL LAW, OR TRIBAL LAW AND IT IS PROHIBITED FROM LIMITING ITS RECOVERY OF DAMAGES FROM A THIRD PARTY UNDER APPLICABLE LAW, THEN THIS SECTION SHALL NOT APPLY TO EITHER SIGNATORY OR THE RCE. NOTHING IN THIS SECTION 7.4 OF THIS COMMON AGREEMENT SHALL BE CONSTRUED TO CREATE LIABILITY FOR A GOVERNMENTAL AGENCY OR INSTRUMENTALITY OR OTHERWISE WAIVE SOVEREIGN IMMUNITY.**

8. RCE Directory

8.1 Access to the RCE Directory Service. The RCE shall provide Signatory with access to the RCE Directory Service once Signatory has been approved for such access by the RCE. The timeframes and requirements for access to the RCE Directory Service and use of the RCE Directory Service are set out in the QTF and the Onboarding & Designation SOP.

8.2 Utilization of the RCE Directory Service **(Required Flow-Down)**. The RCE Directory Service shall be used by Signatory and its Participants and their Subparticipants to create and maintain operational connectivity under the Common Agreement. The RCE is providing Signatory with access to, and the right to use, the RCE Directory Service on the express condition that Signatory only use and disclose information contained in the RCE Directory Service as necessary to advance the intended use of the RCE Directory Service or as required by Applicable Law. For example, Signatory is permitted to disclose information contained in the RCE Directory Service to the

workforce members of its Participant's or Subparticipant's health information technology vendor who are engaged in assisting the Participant or Subparticipant with establishing and maintaining connectivity via this Common Agreement and other Framework Agreements. Further, Signatory shall not use the information contained in the RCE Directory Service for marketing or any form of promotion of its own products and services, unless such use or disclosure is primarily part of an effort by Signatory to expand, or otherwise improve, connectivity via the Common Agreement, and any promotion of Signatory's own products or services is only incidental to that primary purpose. In no event shall Signatory use or disclose the information contained in the RCE Directory Service in a manner that should be reasonably expected to have a detrimental effect on ONC, the RCE, other QHINs and/or their Participants or Subparticipants, or any other individual or organization. For the avoidance of doubt, information contained in the RCE Directory is Confidential Information except to the extent such information meets one of the exceptions to the definition of Confidential Information.

8.3 No Duplicative Entries. Before listing any entity in the RCE Directory Service under Signatory as the QHIN for that Participant or Subparticipant, Signatory must confirm that the Participant or Subparticipant, as the case may be, is not already listed in the RCE Directory Service as a Participant of, or a Subparticipant under, another QHIN. Signatory shall not list in the RCE Directory Service any such duplicative entry as a Participant or Subparticipant of Signatory. Signatory shall not prevent a Participant or Subparticipant from changing the QHIN through which the Participant or Subparticipant engages in exchange under a Framework Agreement.

8.4 Maintenance of RCE Directory Service. The RCE shall provide and maintain the RCE Directory Service on a continuous basis, taking all necessary steps to maintain nominal levels of performance and responsiveness, no less than 99.9% of the time. Communication regarding planned and unplanned downtime should be published to all Participants and Subparticipants promptly, in accordance with generally accepted industry service levels, to ensure that there will be no lapses in service that will materially disrupt the operations of Signatory and other QHINs.

9. TEFCA Exchange Activities

In addition to the requirements below, a QHIN, Participant, or Subparticipant may only Request information under the applicable Framework Agreement 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. Such a QHIN, Participant, or Subparticipant may use a Business Associate, agent, or contractor to make such a Request,

Use, or Disclosure for the applicable Exchange Purpose. For example, only a Health Care Provider as described in the definition of Treatment (or a Business Associate, agent, or contractor acting on that Health Care Provider's behalf) may Request information for the Exchange Purpose of Treatment.

This Common Agreement specifies, among other things, the reasons for which information may be Requested and transmitted from one QHIN to another QHIN. Participants and Subparticipants should understand that, despite their participation under a Framework Agreement, QHINs are prohibited from engaging in QHIN-to-QHIN exchange for any purpose other than an Exchange Purpose under this Common Agreement. The RCE recognizes that Signatory may participate in other health information exchange networks and Signatory's Participants and their Subparticipants also likely participate in other networks, as well as non-network information exchange. This Common Agreement does not affect these other activities or the reasons for which Participants and Subparticipants may request and exchange information within their networks and/or subject to other agreements. Such activities are not in any way limited by the Framework Agreements.

9.1 Utilization of Connectivity Services. Signatory may not utilize the Connectivity Services for any purpose(s) other than the Exchange Purposes. Signatory is responsible for verifying the conformance of all transactions initiated by Signatory's Participants and their Subparticipants prior to transmission via QHIN-to-QHIN exchange, as set forth in the QTF. For the avoidance of doubt, a QHIN may only use the Connectivity Services to initiate a transaction as directed by its Participants or their Subparticipants or if the QHIN itself is authorized under the asserted Exchange Purpose.

9.2 Uses **(Required Flow-Down)**. Signatory may Use TI in any manner that: (i) is not prohibited by Applicable Law; (ii) is consistent with Signatory's Privacy and Security Notice, if applicable; and (iii) is in accordance with Sections 11 and 12 of this Common Agreement, if applicable.

9.3 Disclosures **(Required Flow-Down)**. Signatory may Disclose TI provided such Disclosure: (i) is not prohibited by Applicable Law; (ii) is consistent with Signatory's Privacy and Security Notice, if applicable; and (iii) is in accordance with Sections 11 and 12 of this Common Agreement, if applicable.

9.4 Responses **(Required Flow-Downs)**. Signatory must support **all** Exchange Purposes and must Respond to all Exchange Purposes that are identified as "required" in the Exchange Purposes SOP. Signatory must provide all Required Information that is relevant for a required Exchange Purpose, as may be further specified in an implementation SOP for the applicable Exchange Purpose, in Response to a Request

transmitted via QHIN-to-QHIN exchange, unless providing the Required Information is prohibited by Applicable Law or this Common Agreement or if not providing the Required Information is consistent with all Applicable Law and this Common Agreement.

9.4.1 Exceptions to Required Responses. Notwithstanding the foregoing, Signatory is **permitted but not required** to Respond to a Request transmitted via QHIN-to-QHIN exchange in the circumstances set forth in 9.4.1(i)-(vi) below, provided the Response: (a) is not prohibited by Applicable Law; (b) is consistent with Signatory's Privacy and Security Notice, if applicable; and (c) is in accordance with this Common Agreement.

(i) If Signatory is a Public Health Authority;

(ii) If Signatory utilizes the Government Benefits Determination Exchange Purpose, including such an agency's agent(s)/contractor(s);

(iii) 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 NHE, a Covered Entity, or a Business Associate;

(iv) If the Requested information is not Required Information, provided such response would not otherwise violate the terms of this Common Agreement;

(v) 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); or

(vi) If the Exchange Purpose is authorized but not required at the time of the Request, either under this Common Agreement or the Exchange Purposes SOP.

9.5 Special Legal Requirements **(Required Flow-Down)**. If and to the extent Applicable Law requires that an Individual either consent to, approve, or provide an

authorization for the Use or Disclosure of that Individual's information to Signatory, such as a more stringent state law relating to sensitive health information, then Signatory shall refrain from the Use or Disclosure of such information in connection with this Common Agreement unless such Individual's consent, approval, or authorization has been obtained consistent with the requirements of Applicable Law and Section 11 of this Common Agreement, including without limitation communicated pursuant to the process described in the QTF. Copies of such consent, approval, or authorization shall be maintained and transmitted pursuant to the process described in the QTF by whichever party is required to obtain it under Applicable Law, and Signatory may make such copies of the consent, approval, or authorization available electronically to any QHIN, Participant, or Subparticipant in accordance with the QTF and to the extent permitted by Applicable Law. Signatory shall maintain written policies and procedures to allow an Individual to revoke such consent, approval, or authorization on a prospective basis. If Signatory is an IAS Provider, the foregoing shall not be interpreted to modify, replace, or diminish the requirements set forth in Section 10 of this Common Agreement for obtaining an Individual's express written consent.

10. Individual Access Services (Required Flow-Downs, *if Offering Individual Access Services*)

Nothing in the Privacy and Security Notice or in the Individual's written consent collected by Signatory who is an IAS Provider pursuant to Section 10.2 and Section 10.3 may contradict or be inconsistent with any applicable provision of Sections 10 or 11.

10.1 Individual Access Services (IAS) Offering(s) **(Required Flow-Down)**. Signatory may elect to offer Individual Access Services to any Individual in accordance with the requirements of this section and in accordance with all other provisions of this Common Agreement. Nothing in this Section 10 shall modify, terminate, or in any way affect an Individual's right of access under the HIPAA Privacy Rule at 45 CFR 164.524 with respect to any QHIN, Participant, or Subparticipant that is a Covered Entity or a Business Associate. Nothing in this Section 10 of this Common Agreement shall be construed as an exception or excuse for any conduct by the Signatory that meets the definition of information blocking in 45 CFR 171.103.

10.2 Individual Consent **(Required Flow-Down)**. The Individual requesting Individual Access Services shall be responsible for completing Signatory's own supplied form for obtaining Individual express consent in connection with the Individual Access Services, as set forth below. Signatory may implement secure electronic means

(e.g., secure e-mail, secure web portal) by which an Individual may submit such written consent.

10.3 Written Privacy and Security Notice and Individual Consent **(Required Flow-Downs)**.

10.3.1 If Signatory offers Individual Access Services, it must develop and make publicly available a written privacy and security notice (the "Privacy and Security Notice"). The Privacy and Security Notice must:

(i) Be publicly accessible and kept current at all times, including updated versions;

(ii) Be shared with an Individual prior to the Individual's use/receipt of services from Signatory;

(iii) Be written in plain language and in a manner calculated to inform the Individual of such privacy practices;

(iv) Include a statement regarding whether and how the Individual's TI may be accessed, exchanged, Used, and/or Disclosed by Signatory or by other persons or entities to whom/which Signatory Discloses or provides access to the information, including whether the Individual's TI may be sold at any time (including the future);

(v) Include a statement that Signatory is required to act in conformance with the Privacy and Security Notice and must protect the security of the information it holds in accordance with Section 10 of this Common Agreement;

(vi) Include information regarding whom the Individual may contact within Signatory for further information regarding the Privacy and Security Notice and/or with privacy-related complaints;

(vii) Include a requirement by Signatory to obtain express written consent to the terms of the Privacy and Security Notice from the Individual prior to the access, exchange, Use, or Disclosure (including sale) of the Individual's TI, other than Disclosures that are required by Applicable Law;

(viii) Include information on how the Individual may revoke consent;

(ix) Include an explanation of the Individual's rights, including, at a minimum, the rights set forth in Section 10.4, below;

(x) Include a disclosure of any applicable fees or costs related to IAS including the exercise of rights under Section 10.4 of this Common Agreement; and

(xi) Include an effective date.

The implementation of such Privacy and Security Notice requirements shall be set forth in the IAS SOP. If Signatory is a Covered Entity, then a Notice of Privacy Practices that meets the requirements of 45 CFR § 164.520 **and** meets the requirement of 10.3.1(iv) above can satisfy the Privacy and Security Notice requirements. Nothing in this Section 10.3 reduces a Covered Entity's obligations under the HIPAA Rules.

10.3.2 If Signatory is an IAS Provider, it must collect the Individual's written consent as required under Section 10.3.1(vii) of this Common Agreement at the outset of the Individual's first use of the Individual Access Services and with any material change in the applicable Privacy and Security Notice.

10.4 Individual Rights **(Required Flow-Down)**. Individuals have, and must be clearly informed of, the following rights:

(i) The right to require that **all** of their Individually Identifiable information maintained by Signatory as an IAS Provider be deleted unless such deletion is prohibited by Applicable Law; provided, however, that the foregoing shall not apply to Individually Identifiable information contained in audit logs.

(ii) The right to an export of their Individually Identifiable information in a computable format, including the means to interpret such information.

The rights described in this Section 10.4 shall control over any inconsistent provisions in Section 11.

10.5 Additional Security Requirements for IAS Providers **(Required Flow-Downs)**. In addition to meeting the applicable security requirements set forth in Section 12, if Signatory is an IAS Provider it must further satisfy the requirements of this subsection.

10.5.1 Scope of Security Requirements. If Signatory is an IAS Provider it must comply with the applicable security requirements set forth in this Common Agreement and the security SOPs for **all** Individually Identifiable information they hold, regardless of whether such information is TI.

10.5.2 Encryption. If Signatory is an IAS Provider it is required to encrypt **all** Individually Identifiable information held by Signatory, both in transit and at rest, regardless of whether such data are TI.

10.5.3 TEFCA Security Incident Notice to Affected Individuals. Each Signatory that is an IAS Provider must notify each Individual whose TI has been or is reasonably believed to have been affected by a TEFCA Security Incident involving the IAS Provider. Such notification must be made without unreasonable delay and in no case later than sixty (60) days following Discovery of the TEFCA Security Incident. The notification required under this section must be written in plain language and shall include, to the extent possible:

(i) A brief description of what happened, including the date of the TEFCA Security Incident and the date of its Discovery, if known;

(ii) A description of the type(s) of Unsecured TI involved in the TEFCA Security Incident (such as whether full name, Social Security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(iii) Any steps Individuals should take to protect themselves from potential harm resulting from the TEFCA Security Incident;

(iv) A brief description of what the Signatory involved is doing to investigate the TEFCA Security Incident, to mitigate harm to Individuals, and to protect against any further TEFCA Security Incidents; and

(v) Contact procedures for Individuals to ask questions or learn additional information related to the TEFCA Security Incident, which shall include a telephone number (toll-free), e-mail address, and website with contact information and/or a contact form for the IAS Provider.

To the extent Signatory is already required by Applicable Law to notify an Individual of an incident that would also be a TEFCA Security Incident, this section does not require duplicative notification to that Individual.

10.6 Survival for IAS Providers **(Required Flow-Down)**. The following minimum provisions and their respective minimum time periods shall continue to apply to Signatory to the extent that it is an IAS Provider and survive expiration or termination of the applicable Framework Agreement under which Individual Access Services were provided for the time periods and to the extent described below.

10.6.1 The following Section 10 provisions shall survive the expiration or termination of the applicable Framework Agreement until expiration of the time period specified in the definition of PHI at 45 CFR § 160.103 under Subsection 2(iv) of such definition, i.e., fifty (50) years after the death of the Individual for whom Individual Access Services were provided, even if the information to which the provisions apply is not ePHI:

(i) The terms of the consent under Section 10.2, Individual Consent, and the terms of the Privacy and Security Notice under Section 10.3.1, which sets forth requirements that apply to the Privacy and Security Notice;

(ii) Section 10.3.2, which requires Signatory to collect the Individual's written consent with respect to any material change in the applicable Privacy and Security Notice;

(iii) Section 10.4, Individual Rights; and

(iv) Section 10.5, Additional Security Requirements for IAS Providers.

10.6.2 Section 10.5.3, TEFCA Security Incident Notice to Affected Individuals, shall survive for a period of six (6) years following the expiration or termination of the applicable Framework Agreement.

10.7 Provisions that Apply to Subcontractors and Agents of IAS Providers **(Required Flow-Down).** To the extent that Signatory is an IAS Provider and uses subcontractors or agents with respect to the provision of such Individual Access Services, it shall

include in a written agreement with each such subcontractor or agent a requirement to comply with the following:

(i) To act in accordance with each of the applicable consents required of Signatory under Section 10.2;

(ii) To act in accordance with each of Signatory's applicable Written Privacy and Security Notices pursuant to Section 10.3;

(iii) To act in accordance with Section 10.4 when directed to do so by Signatory;

(iv) With respect to the information for which the subcontractor or agent provides services to Signatory in its role as an IAS Provider, the agent or subcontractor shall implement the applicable security requirements set forth in this Common Agreement (other than Sections 12.1.5, 12.1.6 and 12.3) and the security SOPs for **all** such Individually Identifiable information, regardless of whether such information is TI, to the same extent as they apply to Signatory; provided, however, that for purposes of the Flow-Down Provisions of this Section 10.7, if the IAS Provider is a Participant or Subparticipant, only Sections 12.1.4 and 12.2 shall apply;

(v) To encrypt **all** Individually Identifiable information both in transit and at rest, regardless of whether such data are TI pursuant to Section 10.5.2; and

(vi) To notify Signatory that is an IAS Provider for which it provides services with respect to each Individual whose TI has been or is reasonably believed to have been affected by a TEFCA Security Incident involving the subcontractor or agent in the manner and within the timeframe specified pursuant to Section 10.5.3.

Each agreement between Signatory and a subcontractor or agent with respect to the provision of Individual Access Services shall also provide that subsections (i) through (v) above shall continue in effect after termination or expiration of such agreement at least until expiration of the time period specified in the definition of PHI at 45 CFR § 160.103 under subsection 2(iv) of such definition, i.e., fifty (50) years after the death of the Individual to whom the information relates. Each such agreement shall also provide that subsection (vi) above shall survive for at least six (6) years following the termination or expiration of such agreement.

11. Privacy

11.1 Compliance with the HIPAA Privacy Rule **(Required Flow-Down)**. If Signatory is a NHE (but not to the extent that it is acting as an entity entitled to make a Government Benefits Determination under Applicable Law, a Public Health Authority, or a Government Health Care Entity), then it shall comply with the provisions of the HIPAA Privacy Rule listed below with respect to all Individually Identifiable information that Signatory reasonably believes is TI as if such information is Protected Health Information and Signatory is a Covered Entity. Such compliance shall be consistent with Section 13.2 (Compliance with Specific Obligations) and enforced as part of its obligations pursuant to this Common Agreement.

11.1.1 From 45 CFR § 164.502, General Rules **(Required Flow-Down)**:

- Subsection (a)(1) – Dealing with permitted Uses and Disclosures, **but only to the extent Signatory is authorized to engage in the activities described in this subsection of the HIPAA Privacy Rule for the applicable Exchange Purpose.**
- Subsection (a)(2)(i) – Requiring Disclosures to Individuals
- Subsection (a)(3) – Business Associates
- Subsection (a)(5) – Dealing with prohibited Uses and Disclosures
- Subsection (b) – Dealing with the Minimum Necessary standard
- Subsection (c) – Dealing with agreed-upon restrictions
- Subsection (d) – Dealing with deidentification and re-identification of information
- Subsection (e) – Dealing with Business Associate contracts
- Subsection (f) – Dealing with deceased persons' information
- Subsection (g) – Dealing with personal representatives
- Subsection (h) – Dealing with confidential communications
- Subsection (i) – Dealing with Uses and Disclosures consistent with notice
- Subsection (j) – Dealing with Disclosures by whistleblowers

11.1.2 45 CFR § 164.504, Organizational Requirements **(Required Flow-Down)**.

11.1.3 45 CFR § 164.508, Authorization Required **(Required Flow-Down)**. Notwithstanding the foregoing, the provisions of Sections 10.2 and 10.3 shall

control and this Section 11.1.3 shall not apply with respect to an IAS Provider that is a NHE.

11.1.4 45 CFR § 164.510, Uses and Disclosures Requiring Opportunity to Agree or Object **(Required Flow-Down)**. Notwithstanding the foregoing, an IAS Provider that is a NHE but is not a Health Care Provider shall not have the right to make the permissive Disclosures described in § 164.510(3) - Emergency circumstances; provided, however, that an IAS Provider is not prohibited from making such a Disclosure if the Individual has consented to the Disclosure pursuant to Section 10 of this Common Agreement.

11.1.5 45 CFR § 164.512, Authorization or Opportunity to Object Not Required **(Required Flow-Down)**. Notwithstanding the foregoing, an IAS Provider that is a NHE but is not a Health Care Provider shall not have the right to make the permissive Disclosures described in § 164.512(c) - Standard: Disclosures about victims of abuse, neglect or domestic violence; § 164.512 Subsection (d) - Standard: Uses and disclosures for health oversight activities; and § 164.512 Subsection (j) - Standard: Uses and disclosures to avert a serious threat to health or safety; provided, however, that an IAS Provider is not prohibited from making such a Disclosure(s) if the Individual has consented to the Disclosure(s) pursuant to Section 10 of this Common Agreement.

11.1.6 From 45 CFR § 164.514, Other Requirements Relating to Uses and Disclosures **(Required Flow-Down)**:

- Subsections (a)-(c) – Dealing with de-identification requirements that render information **not** Individually Identifiable for purposes of this Section 11 and TEFCA Security Incidents
- Subsection (d) – Dealing with Minimum Necessary requirements
- Subsection (e) – Dealing with Limited Data Sets

11.1.7 45 CFR § 164.522, Rights to Request Privacy Protections **(Required Flow-Down)**.

11.1.8 45 CFR § 164.524, Access of Individuals **(Required Flow-Down)**, except that an IAS Provider that is a NHE shall be subject to the requirements of Section 10 with respect to access by Individuals for purposes of Individual Access Services and not this Section 11.1.8.

11.1.9 45 CFR § 164.528, Accounting of Disclosures **(Required Flow-Down)**.

11.1.10 From 45 CFR § 164.530, Administrative Requirements **(Required Flow-Down)**:

- Subsection (a) – Dealing with personnel designations
- Subsection (b) – Dealing with training
- Subsection (c) – Dealing with safeguards
- Subsection (d) – Dealing with complaints
- Subsection (e) – Dealing with sanctions
- Subsection (f) – Dealing with mitigation
- Subsection (g) – Dealing with refraining from intimidating or retaliatory acts
- Subsection (h) – Dealing with waiver of rights
- Subsection (i) – Dealing with policies and procedures
- Subsection (j) – Dealing with documentation

11.2 Written Privacy Policy **(Required Flow-Down)**. Signatory must develop, implement, make publicly available, and act in accordance with a written privacy policy describing its privacy practices with respect to Individually Identifiable information that is Used or Disclosed pursuant to this Common Agreement. Signatory can satisfy the written privacy policy requirement by including applicable content consistent with the HIPAA Rules into its existing privacy policy, except as otherwise stated herein with respect to IAS Providers. This written privacy policy requirement does not supplant the HIPAA Privacy Rule obligations of a QHIN, Participant, or a Subparticipant that is a Covered Entity to post and distribute a Notice of Privacy Practices that meets the requirements of 45 CFR § 164.520. If Signatory is a Covered Entity, then this written privacy practices requirement can be satisfied by its Notice of Privacy Practices. If Signatory is an IAS Provider, then the written privacy practices requirement **must** be in the form of a Privacy and Security Notice that meets the requirements of Section 10.3 of this Common Agreement.

12. Security

12.1 General Security Requirements. Signatory shall comply with the HIPAA Security Rule as if the HIPAA Security Rule applied to Individually Identifiable information that is TI regardless of whether Signatory is a Covered Entity or a Business Associate. Signatory shall also comply with the security requirements stated in Section 12 of this Common Agreement and specific additional requirements as described in the

QTF and applicable SOPs, to the extent that such requirements are not already included in the HIPAA Security Rule, with respect to all Individually Identifiable information that is TI as if such information were Protected Health Information and Signatory were a Covered Entity or Business Associate. Notwithstanding anything else in this Section 12, none of these requirements shall apply to any federal agency or Public Health Authority.

12.1.1 Cybersecurity Coverage. In accordance with the Cybersecurity Coverage SOP, Signatory shall maintain, throughout the term of this Common Agreement: (i) a policy or policies of insurance for cyber risk and technology errors and omissions; (ii) internal financial reserves to self-insure against a cyber-incident; or (iii) some combination of (i) and (ii).

12.1.2 Cybersecurity Certification. Signatory shall achieve and maintain third-party certification to an industry-recognized cybersecurity framework demonstrating compliance with all relevant security controls, as set forth in the applicable SOP.

12.1.3 Annual Security Assessments. Signatory must obtain a third-party security assessment and technical audit no less often than annually and as further described in the applicable SOP. Signatory must also provide evidence of compliance with this section and, if applicable, of appropriate mitigation efforts in response to the findings of the security assessment and/or technical audit within thirty (30) days to the RCE as specified in the SOP.

12.1.4 Participants and Subparticipants **(Required Flow-Down)**. Signatory shall require in its Participant-QHIN Agreements that its Participants implement and maintain, and require their Subparticipants to implement and maintain, appropriate security controls for TI that are commensurate with risks to the confidentiality, integrity, and/or availability of the TI. If any Participant or Subparticipant is a NHE, it shall be required to comply with the HIPAA Security Rule provisions with respect to all Individually Identifiable information that the Participant or Subparticipant reasonably believes is TI as if such information were Protected Health Information and the Participant or Subparticipant were a Covered Entity or Business Associate. Signatory shall further require that its Participants implement and maintain, and that its Participants require their Subparticipants to implement and maintain, any additional security requirements that may be set forth in an SOP applicable to Participants and Subparticipants. Such compliance shall be enforced as part of the Participants' and Subparticipants' obligations pursuant to the Framework Agreements.

12.1.5 Security Resource Support to Participants. Signatory shall make available to its Participants: (i) security resources and guidance regarding the protection of TI applicable to the Participants' participation in the QHIN under the applicable Framework Agreement; and (ii) information and resources that the RCE or Security Council makes available to Signatory related to promotion and enhancement of the security of TI under the Framework Agreements.

12.1.6 Chief Information Security Officer. The RCE shall designate a person to serve as the Chief Information Security Officer (CISO) for activities conducted under the Framework Agreements. This may be either an employee or independent contractor of the RCE. The RCE's CISO will be responsible for monitoring and maintaining the overall security posture of activities conducted under the Framework Agreements and making recommendations to all QHINs regarding changes to baseline security practices required to address changes to the threat landscape. Signatory agrees that it, and not the RCE, is ultimately responsible for the security posture of Signatory's network and the activities conducted by Signatory under the Participant-QHIN Agreements to which Signatory is a party, as well as the Participant-Subparticipant Agreements its Participants enter into and all Downstream Subparticipant Agreements that its Participants' Subparticipants enter into. Signatory shall also designate a person to serve as its CISO for purposes of Signatory's participation in QHIN-to-QHIN exchange. The RCE shall establish a Cybersecurity Council to enhance cybersecurity commensurate with the risks of the activities conducted under the Framework Agreements as more fully set forth in an SOP.

12.2 TI Outside the United States **(Required Flow-Down)**. Signatory shall not Use TI outside the United States or Disclose TI to any person or entity outside the United States except to the extent such Use or Disclosure is permitted or required by Applicable Law and except to the extent the Use or Disclosure is conducted in conformance with the HIPAA Security Rule, regardless of whether Signatory is a Covered Entity or Business Associate. Signatory shall evaluate the risks of any extraterritorial Uses and/or Disclosures of TI, if applicable, as part of an annual security assessment and prior to any new or substantially different type of non-U.S. Use(s) or Disclosure(s). Such security assessment shall include a risk assessment to evaluate whether the Uses or Disclosures of Individually Identifiable information that is reasonably believed to be TI by or to persons or entities outside the United States satisfies the requirements of the HIPAA Security Rule. The foregoing does not modify or eliminate any provision of Applicable Law that does not permit a Signatory

to Disclose Individually Identifiable information to a person or entity outside the United States or that imposes conditions or limitations on such Disclosure.

12.3 TEFCA Security Incident Notification. As soon as reasonably practicable, but not more than five (5) calendar days after determining that an TEFCA Security Incident has occurred, Signatory shall provide notification to the RCE and to all QHINs that are likely impacted, whether directly or by nature of one of the other QHIN's Participants or Subparticipants, of the TEFCA Security Incident. Such notification must include sufficient information for the RCE and others affected to understand the nature and likely scope of the TEFCA Security Incident. Signatory shall supplement the information contained in the notification as it becomes available and cooperate with the RCE, and with other QHINs, Participants, and Subparticipants that are likely impacted by the TEFCA Security Incident.

12.3.1 Receiving TEFCA Security Incident Notification. Signatory shall implement a reporting protocol by which other QHINs can provide Signatory with notification of a TEFCA Security Incident. In the event that the TEFCA Security Incident involves TI that is de-identified in accordance with the de-identification standard provided at 45 CFR § 164.514(a), then no such reporting obligation shall exist.

12.3.2 Vertical Reporting of TEFCA Security Incident(s). Signatory shall require that each Participant with which it has entered into a Participant-QHIN Agreement:

(i) Notify Signatory and Participant's Subparticipants of any TEFCA Security Incident the Participant experiences in accordance with the timing and content requirements stated in Section 12.3;

(ii) Require that each Subparticipant with which the Participant enters into a Participant-Subparticipant Agreement report any TEFCA Security Incident experienced by or reported to the Subparticipant to the Participant and to the Subparticipant's Downstream Subparticipants in accordance with the timing and content requirements stated in Section 12.3;

(iii) Require that each Subparticipant with which the Participant enters into a Participant-Subparticipant Agreement require that its Downstream Subparticipants report any TEFCA Security Incident experienced by or reported to the Downstream Subparticipant to the Upstream Subparticipant and to its own

Downstream Subparticipants, in accordance with the timing and content requirements stated in Section 12.3.

(iv) Notify Signatory of any TEFCA Security Incident reported to the Participant by one of its Subparticipants.

12.3.3 Compliance with Notification Under Applicable Law. Nothing in this Section 12.3 shall be deemed to modify or replace any breach notification requirements that Signatory may have under the HIPAA Rules, the FTC Rule, and/or other Applicable Law. To the extent Signatory is already required by Applicable Law to notify a Participant, Subparticipant, and/or another QHIN of an incident that would also be a TEFCA Security Incident, this section does not require duplicative notification.

13. General Obligations

13.1 Compliance with Applicable Law and the Framework Agreements **(Required Flow-Down)**. Signatory shall comply with all Applicable Law and shall implement and act in accordance with any provision required by this Common Agreement, including all applicable SOPs and provisions of the QTF.

13.2 Compliance with Specific Obligations.

13.2.1 Responsibility of the RCE. The RCE shall be responsible for taking reasonable steps to confirm that Signatory is abiding by the obligations under this Common Agreement and all applicable SOPs. In the event that the RCE becomes aware of a material non-compliance with any of the obligations stated in the Common Agreement or any of the applicable SOPs by Signatory, then the RCE shall promptly notify Signatory in writing. Such notice shall inform Signatory that its failure to correct any such deficiencies within the timeframe established by the RCE shall constitute a material breach of this Common Agreement, which may result in termination of this Common Agreement.

13.2.2 Responsibility of Signatory **(Required Flow-Down)**. Signatory shall be responsible for taking reasonable steps to confirm that all of its Participants are abiding by the Required Flow-Downs and all applicable SOPs. In the event that Signatory becomes aware of a material non-compliance by one of its Participants, then Signatory shall promptly notify the Participant in writing. Such notice shall inform the Participant that its failure to correct any

such deficiencies within the timeframe established by Signatory shall constitute a material breach of the Participant-QHIN Agreement, which may result in early termination of said agreement.

13.3 Flow-Down Rights to Suspend **(Required Flow-Downs)**.

13.3.1 Suspension Rights Granted to RCE. Each Participant-QHIN Agreement, Participant-Subparticipant Agreement, and Downstream Subparticipant Agreement shall include a grant of authority to the RCE to suspend each party's right to engage in any QHIN-to-QHIN exchange activities if: (i) there is an alleged violation of such agreement or of Applicable Law by the party/parties; (ii) there is a cognizable threat to the security of the information that the RCE reasonably believes is TI transmitted pursuant to such agreement or to the infrastructure of the QHIN; or (iii) such suspension is in the interests of national security as directed by an agency of the United States government.

13.3.2 Suspension Rights Granted to Signatory. Each of the aforementioned Framework Agreements shall also grant Signatory the same authority as the RCE to suspend a party's right to engage in any activities under the Framework Agreement if any of the circumstances described in subsections 13.3.1 (i)-(iii) above occur with respect to any Participant and/or Subparticipant of Signatory.

(i) Signatory *may* exercise such right to suspend based on its own determination that any of the circumstances described in subsections 13.3.1 (i)-(iii) above occurred with respect to any Participant and/or Subparticipant of Signatory.

(ii) Signatory ***must*** exercise such right to suspend if directed to do so by the RCE based on the RCE's determination that suspension is warranted based on any of the circumstances described in subsections 13.3.1 (i)-(iii) above with respect to any Participant and/or Subparticipant of Signatory. If the suspension of any Participant and/or Subparticipant of Signatory is at the direction of the RCE, Signatory must effectuate such suspension as soon as practicable and not longer than within twenty-four (24) hours of the RCE having directed the suspension, unless the RCE specifies a longer period of time is permitted to effectuate the suspension.

13.4 Survival for Participants and Subparticipants (**Required Flow-Downs**). The following are the minimum survival provisions and respective minimum time periods that shall be included in each of the Framework Agreements other than this Common Agreement. Signatory shall include at least the following survival provisions in all of its Participant-QHIN Agreements and shall require its Participants to include the following minimum survival provisions and minimum survival time periods in all their Participant-Subparticipant Agreements as Required Flow-Downs so that such provisions will also be included as minimum survival provisions and minimum survival time periods in all Downstream Subparticipant Agreements.

13.4.1 Section 7.1, Confidential Information, shall survive for a period of six (6) years following the expiration or termination of the applicable Framework Agreement.

13.4.2 Section 10.6, Survival for IAS Providers, to the extent that the Participant or Subparticipant is an IAS Provider, shall survive following the expiration or termination of the applicable Framework Agreement for the respective time periods set forth in Section 10.6.

13.4.3 Section 11, Privacy, to the extent that the Participant or Subparticipant is subject to Section 11, said Section shall survive the expiration or termination of the applicable Framework Agreement until the expiration of the time period specified in the definition of PHI at 45 CFR § 160.103 under Subsection 2(iv) of such definition, i.e., fifty (50) years after the death of the Individual to whom the information covered by Section 11 relates.

13.4.4 Section 12.1.4, Participants and Subparticipants, to the extent that the Participant or Subparticipant is subject to Section 12.1.4, said Section shall survive the expiration or termination of the applicable Framework Agreement until the expiration of the time period specified in the definition of PHI at 45 CFR § 160.103 under Subsection 2(iv) of such definition, i.e., fifty (50) years after the death of the Individual to whom the information covered by Section 12.1.4 relates.

13.4.5 The requirements of Section 12.3.2, Vertical Reporting of TEFCA Security Incident(s), shall survive for a period of six (6) years following the expiration or termination of the applicable Framework Agreement.

14. Specific QHIN Obligations

14.1 Transparency – Access to Participant-QHIN Information. If either ONC or the RCE has a reasonable basis to believe that one or more of the following situations exist with respect to Signatory, then Signatory shall make available, upon written request, copies of its Participant-QHIN Agreements and information relating to the exchange of TI and the circumstances giving rise to the basis for such request. The foregoing shall be subject to Signatory's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges but only to the extent that such information is material to the defense of a substantiated claim asserted by a third party. Such situations include: (i) an alleged violation of this Common Agreement or Applicable Law; or (ii) a threat to the security of information that the RCE or ONC reasonably believes is TI transmitted pursuant to the Framework Agreements or to the infrastructure supporting QHIN-to-QHIN exchange. The right of Signatory to restrict or condition its cooperation or disclosure of its Participant-QHIN Agreement(s) and information relating to the exchange of TI in the interest of preserving privileges shall not apply to a disclosure that is requested in the interest of national security.

14.2 Compliance with Standard Operating Procedures. The RCE shall adopt Standard Operating Procedures (SOPs) to provide detailed guidance on specific aspects of the exchange activities under this Common Agreement that are binding on the RCE, Signatory and, as applicable, Participants and Subparticipants. The SOPs are incorporated by reference into this Common Agreement, and Signatory shall comply with all SOPs that are applicable to it and shall require that its Participants and their Subparticipants agree in writing to comply with all applicable SOPs. If Signatory or its Participants or Subparticipants fail to comply with any applicable SOP, the RCE may take corrective action, which will include requiring steps to bring the organization into compliance with the SOP and may include requiring Signatory to suspend the ability of a Participant or Subparticipant to exchange information under the Framework Agreement(s) until the non-compliance is corrected to the satisfaction of the RCE, suspending Signatory's right to exchange information under the Common Agreement or Signatory may have its right to exchange information under the Common Agreement terminated or be required to ensure the termination of its Participant's or a Subparticipant's right to exchange information under one of the other Framework Agreements. RCE shall adopt an SOP that provides detailed information about sanctions for non-compliance with an SOP. Nothing in this Section 14.2 of this Common Agreement limits the RCE's rights to terminate this Common Agreement under Section 16.3.2 or 16.3.3 of this Common Agreement.

14.3 Incorporation of Required Flow-Downs in Framework Agreements. In addition to the obligations of Signatory with respect to its Participants stated throughout in this Common Agreement:

(i) Signatory shall be responsible for incorporating the Required Flow-Downs into all Participant-QHIN Agreements.

(ii) Signatory shall require that each of its Participants be responsible for incorporating the Required Flow-Downs into all Participant-Subparticipant Agreements.

(iii) Signatory shall further require that each of its Participants be responsible for requiring that each of their Subparticipants incorporate the Required Flow-Downs into all Downstream Subparticipant Agreements, if any.

14.4 Compliance with the QHIN Technical Framework. Signatory shall meet the requirements of the then-applicable QTF. Signatory is required to comply with any updates to the QTF by the applicable date established by the RCE and approved by ONC.

15. Dispute Resolution

15.1 Acknowledgement and Consent to Dispute Resolution Process. Signatory acknowledges that it may be in its best interest to resolve Disputes related to the Common Agreement through a collaborative, collegial process rather than through civil litigation. Signatory has reached this conclusion based upon the fact that the legal and factual issues related to the exchange and related activities under the Common Agreement are unique, novel, and complex, and limited case law exists that addresses the legal issues that could arise in connection with this Common Agreement. Therefore, Signatory shall submit Disputes to the RCE to be addressed by the non-binding Dispute resolution process set forth in an SOP (the "Dispute Resolution Process"). Notwithstanding, Signatory understands that the Dispute Resolution Process does not supersede or replace any oversight, investigatory, enforcement, or other administrative actions or processes that may be taken by the relevant authority, whether or not arising out of or related to the circumstances giving rise to the Dispute. RCE and Signatory are committed to promptly and fairly resolving Disputes.

To that end, Signatory shall use its best efforts to resolve Disputes that may arise with other QHINs, their respective Participants, or the RCE through informal

discussions before seeking to invoke the Dispute Resolution Process. If the Dispute cannot be resolved through cooperation between Signatory and the other QHIN(s), Signatory may, on its own behalf or on behalf of its Participant(s), choose to submit the Dispute to the Dispute Resolution Process. Likewise, Signatory, on its own behalf and on behalf of its Participant(s), will seek to resolve Disputes involving the RCE through good-faith informal discussions with the RCE prior to invoking the Dispute Resolution Process.

Under no circumstances will the Dispute Resolution Process give the RCE any power to assess monetary damages against any party to the Dispute Resolution Process including, without limitation, Signatory or its Participants or any other QHIN or its Participants. Except in accordance with Section 15.2, if Signatory refuses to participate in the Dispute Resolution Process, such refusal shall constitute a material breach of this Common Agreement and may be grounds for termination of Signatory's participation in QHIN-to-QHIN exchange.

15.2 Injunctive Relief.

15.2.1 Notwithstanding Section 15.1, Signatory shall be relieved of its obligation to participate in the Dispute Resolution Process if Signatory: (i) makes a good faith determination that is based upon available information or other evidence that another QHIN's or its Participants' acts or omissions will cause irreparable harm to Signatory or another organization or person (e.g., another QHIN or its Participant or an Individual); and (ii) pursues immediate injunctive relief against such QHIN or its Participant in a court of competent jurisdiction in accordance with Section 18.3. Signatory must inform RCE of such action within two (2) business days of filing for the injunctive relief and of the result of the action within twenty-four (24) hours of a court of competent jurisdiction granting or denying injunctive relief.

15.2.2 If the injunctive relief sought in Section 15.2.1 is not granted and Signatory chooses to pursue the Dispute, the Dispute must be submitted to the Dispute Resolution Process in accordance with Section 15.1.

15.3 Activities during Dispute Resolution Process. The pendency of a Dispute under this Common Agreement has no effect on either Party's obligations hereunder, unless Signatory terminates its rights in accordance with Section 16.2 or 16.3.1 or is suspended in accordance with Section 16.4.2.

15.4 Implementation of Agreed Upon Resolution. If, at any point during the Dispute Resolution Process, Signatory and all other parties to the Dispute accept a proposed

resolution of the Dispute, Signatory and RCE each agree to implement the terms of the resolution within the agreed-upon timeframe to the extent applicable to each of them.

15.5 Reservation of Rights. If, following the completion of the Dispute Resolution Process, in the opinion of Signatory, the Dispute Resolution Process failed to adequately resolve the Dispute, Signatory may pursue any remedies available to it in a court of competent jurisdiction in accordance with Section 18.3.

15.6 Escalation and Reporting of Disputes to ONC.

15.6.1 Escalation of Certain Disputes to ONC. If Signatory has reason to believe that: (i) the RCE is acting in a discriminatory manner or in violation of the RCE's conflict of interest policies; or (ii) the RCE has not acted in accordance with its obligations stated in this Common Agreement, then Signatory shall have the right, on its own behalf and on behalf of its Participants, to make a complaint to ONC. The complaint shall identify the parties to the Dispute, a description of the Dispute, a summary of each party's position on the issues included in the Dispute, the final disposition of the Dispute, and the basis for the RCE's alleged misconduct. The RCE and Signatory shall each also promptly provide such additional information as may be reasonably requested by ONC in order to consider and resolve the issues raised for review. Since this complaint may include PHI and may include Confidential Information, the RCE will work with ONC to develop mechanisms to protect the confidentiality of this information. Such protective mechanisms and the process for escalating a complaint to ONC are set forth in an SOP.

15.6.2 Reporting of Anonymized Dispute Information to ONC. As part of the RCE's communications with ONC, within fifteen (15) business days after the end of each calendar quarter, the RCE reports the following information relating to each Dispute that has been submitted through the Dispute Resolution Process in an anonymized format to ONC: (i) identification of whether the parties to the Dispute are QHIN(s) only, or whether the Dispute also involves Participant(s); (ii) a description of the Dispute with reasonable specificity; and (iii) the final disposition of the Dispute.

16. Stability of the QHIN Network

16.1 Term. This Common Agreement shall commence on the Effective Date and shall remain in effect until it is terminated by either Party in accordance with the terms of this Common Agreement.

16.2 Withdrawal and Termination Prior to QHIN Designation.

16.2.1 By Signatory. Signatory may withdraw from Onboarding and terminate this Common Agreement at any time before it is Designated if it determines that it cannot meet the requirements of being a QHIN or if it chooses not to continue to seek status as a QHIN. Signatory must provide at least fifteen (15) calendar days' written notice to RCE of its intention to withdraw from Onboarding and terminate this Common Agreement.

16.2.2 By the RCE. If Signatory fails to complete the Onboarding requirements within the timeframe specified in the Onboarding & Designation SOP, the RCE may withdraw Signatory from Onboarding and terminate this Common Agreement upon fifteen (15) calendar days' written notice to Signatory that Signatory has failed to meet the Onboarding requirements and, therefore, cannot be Designated. The foregoing shall not be interpreted as precluding Signatory from reapplying for Designation at a future time.

16.3 Termination.

16.3.1 Termination by Signatory. Signatory may terminate this Common Agreement at any time without cause by providing ninety (90) days' prior written notice to RCE. Signatory may also terminate for cause if the RCE commits a material breach of the Common Agreement, and the RCE fails to cure its material breach within thirty (30) days of Signatory providing written notice to RCE of the material breach; provided, however, that if RCE is diligently working to cure its material breach at the end of this thirty- (30-) day period, then Signatory must provide the RCE with up to another thirty (30) days to complete its cure.

16.3.2 Termination by the RCE. RCE may not terminate this Common Agreement without cause as described in this Section 16.3.2 or Section 16.3.3 of this Common Agreement. RCE may terminate this Common Agreement with immediate effect by giving notice to Signatory if: (i) Signatory is in material breach of any of the terms and conditions of this Common Agreement and fails to remedy such breach within thirty (30) days after receiving notice of

such breach; provided, however, that if Signatory is diligently working to cure its material breach at the end of this thirty- (30-) day period, then RCE must provide Signatory with up to another thirty (30) days to complete its cure; or (ii) Signatory breaches a material provision of this Common Agreement where such breach is not capable of remedy.

16.3.3 Termination by RCE if the RCE Ceases to be Funded. The Parties acknowledge that the RCE's activities under this Common Agreement are supported by ONC funding. If this funding ceases, there are no guarantees that the RCE will continue unless a financial sustainability model has been put in place. If federal funding ceases, or if the available funding is not sufficient to provide the necessary funding to support operation of the RCE and there is no successor RCE, then the RCE may terminate this Common Agreement by providing one hundred and eighty (180) days' prior written notice to Signatory.

16.3.4 Termination by Mutual Agreement. The Parties may terminate this Common Agreement at any time and for any reason by mutual, written agreement.

16.3.5 Effect of Termination of the Common Agreement.

(i) Upon termination of this Common Agreement for any reason, RCE shall promptly remove Signatory and its Participants and Subparticipants from the RCE Directory Service and any other lists of QHINs that RCE maintains.

(ii) Upon termination of this Common Agreement for any reason, Signatory shall, without undue delay, (a) remove all references that identify it as a QHIN from all media, and (b) cease all use of any material, including but not limited to product manuals, marketing literature, and web content that identifies it as a QHIN. Within twenty (20) business days of termination of this Common Agreement, Signatory shall confirm to RCE, in writing, that it has complied with this Subsection.

(iii) To the extent Signatory stores TI, such TI may not be distinguishable from other information maintained by Signatory. When the TI is not distinguishable from other information, it is not possible for Signatory to return or destroy TI it maintains upon termination or expiration of this Common Agreement. Upon termination or expiration of this Common Agreement, if Signatory

is subject to Section 11 of this Common Agreement, such sections shall continue to apply so long as the information would be ePHI if maintained by a Covered Entity or Business Associate. The protections required under the HIPAA Security Rule shall also continue to apply to all TI that is ePHI, regardless of whether Signatory is a Covered Entity or Business Associate.

(iv) In no event shall Signatory be entitled to any refund of any fees that it has paid the RCE prior to termination.

16.4 Suspension.

16.4.1 Suspension by RCE. RCE may suspend Signatory's ability to engage in exchange activities under the Common Agreement if RCE determines, following completion of a preliminary investigation, that Signatory is responsible for a Threat Condition. To the extent that RCE determines that one of Signatory's Participants or Subparticipants has done something or failed to do something that results in a Threat Condition, RCE may suspend, or the RCE may direct that Signatory suspend, that Participant's or Subparticipant's ability to engage in exchange activities under the Common Agreement. RCE will make a reasonable effort to notify Signatory in advance of RCE's intent to suspend Signatory or one of Signatory's Participants or Subparticipants, including notice of the Threat Condition giving rise to such suspension. If advance notice is not reasonably practicable under the circumstances, the RCE will notify Signatory of the suspension, and the Threat Condition giving rise thereto, as soon as practicable following the suspension. Upon suspension of either Signatory or one of Signatory's Participants or Subparticipants, RCE will work collaboratively with Signatory to resolve the issue leading to the suspension. RCE shall adopt an SOP to address specific requirements and timelines related to suspension.

16.4.2 Selective Suspension by Signatory. Signatory may, in good faith and to the extent permitted by Applicable Law, determine that it must suspend exchanging with another QHIN with which it is otherwise required to exchange in accordance with an SOP because of reasonable and legitimate concerns related to the privacy and security of information that is exchanged. If Signatory makes this determination, it is required to promptly notify the RCE and the QHIN that Signatory is suspending of its decision and the reason(s) for making the decision. If Signatory makes the decision to suspend, it is required, within thirty (30) days, to initiate the Dispute Resolution Process in order to resolve whatever issues led to the decision to

suspend, or end its suspension and resume exchanging with the other QHIN. Provided that Signatory selectively suspends exchanging with another QHIN in accordance with this Section and in accordance with Applicable Law, such selective suspension shall not be deemed a violation of Section 6.2.2.

16.4.3 Additional Suspension Rights of RCE. Notwithstanding anything to the contrary set forth herein, the RCE retains the right to suspend any exchange activity under the Common Agreement (i) upon ten (10) days' prior notice if the RCE determines that Signatory has created a situation in which the RCE may suffer material harm and suspension is the only reasonable step that the RCE can take to protect itself; or (ii) immediately if the RCE determines that the safety or security of any person or the privacy or security of TI and/or Confidential Information is threatened. In the case of an immediate suspension under this section, the RCE will provide notice as soon as practicable following the suspension.

16.4.4 Effect of Suspension. The suspension of Signatory's ability to participate in any activity under this Common Agreement pursuant to this section has no effect on Signatory's other obligations hereunder, including, without limitation, obligations with respect to privacy and security. During any suspension pursuant to this section, Signatory's inability to exchange information under this Common Agreement or comply with those terms of this Common Agreement that require information exchange shall not be deemed a breach of this Common Agreement. In the event of suspension of Signatory's ability to participate in exchange activities under this Common Agreement, Signatory shall communicate to its Participants, and require that they communicate to their Subparticipants, that all QHIN-to-QHIN exchange on behalf of Signatory's Participants and Subparticipants will also be suspended during any period of Signatory's suspension.

16.5 Successor RCE and Transition.

16.5.1 Selection of RCE and Successor RCE(s) and Continuing Obligations. Signatory agrees that ONC had the right to select the initial RCE and that ONC shall have the right to select any successor RCE and/or to act as an interim RCE until such successor RCE has been selected. Signatory further agrees to work cooperatively with the RCE and any interim or successor RCE selected by ONC in accordance with this Common Agreement. Additionally, Signatory shall continue to abide by the provisions of this Common Agreement during the transition to any interim or successor RCE.

16.5.2 RCE Transition Services. In the event that ONC selects a successor RCE, the then-current RCE will be required to continue supporting functions throughout a ninety- (90-) day closeout period. If ONC acts as an interim RCE prior to the appointment of a successor RCE, the references to successor RCE shall apply to ONC as the interim RCE.

17. Fees

17.1 Fees Paid by QHINs to the RCE. Signatory shall pay the fees set forth on Schedule 1 attached hereto (the "QHIN Fees"). RCE shall invoice Signatory for all Fees in accordance with Schedule 1. Unless otherwise set forth in Schedule 1, invoices shall be due and payable by Signatory within sixty (60) days after receipt thereof unless Signatory notifies RCE in writing that it is contesting the accuracy of the invoice and identifies the specific inaccuracies that it asserts. QHIN Fees contested under this Section shall be resolved between Signatory and RCE as stated in the applicable SOP. Other than with regard to invoiced amounts that are contested in good faith, any collection costs, attorneys' fees or other expenses reasonably incurred by RCE in collecting amounts due under this Common Agreement are the responsibility of Signatory. If Signatory fails to pay any undisputed QHIN Fees when due hereunder, RCE has the right to suspend Signatory's ability to participate in any exchange activity under this Common Agreement. Prior to taking any action against Signatory for non-payment, including suspension, RCE shall provide Signatory ten (10) days' prior written notice. If Signatory makes payment within ten (10) days of receiving written notice, RCE will not suspend Signatory's ability to participate in any exchange activity under this Common Agreement. If Signatory fails to make payment within ten (10) days of receiving notice, then the RCE may implement the suspension or may terminate Signatory's ability to participate in any exchange activity under this Common Agreement.

17.1.1 Changes to QHIN Fees. Schedule 1 may be updated by the RCE from time-to-time in relation to operational costs, availability of ONC funding, and other market factors in order to ensure the sustainability of the activities conducted under the Framework Agreements. In light of the foregoing, changes to Schedule 1 are not subject to the change management process set forth in Section 5. The RCE shall provide Signatory not less than ninety (90) days' advance written notice of any adjustments to the QHIN Fees set forth in Schedule 1.

17.2 Fees Paid by QHINs to Other QHINs. Signatory is prohibited from charging fees to other QHINs for any exchange of information using the Connectivity Services.

18. Contract Administration

18.1 Authority to Execute. Signatory warrants and represents that it has the full power and authority to execute this Common Agreement and that any representative of Signatory who executes this Common Agreement has full power and authority to do so on behalf of Signatory.

18.2 Notices. All notices to be made under this Common Agreement shall be given in writing to Signatory and RCE at the addresses set forth following each Party's signature, and shall be deemed given: (i) upon delivery, if personally delivered; (ii) upon delivery by overnight delivery service such as UPS or FEDEX or another recognized commercial carrier; (iii) upon the date indicated on the return receipt, when sent by the United States Postal Service Certified Mail, return receipt requested; and (iv) if by facsimile telecommunication or other form of electronic transmission, upon receipt when the sending facsimile machine or electronic mail address receives confirmation of receipt by the receiving facsimile machine or electronic mail address.

SIGNATORY: _____

NOTICE TO:

Name/Title: _____

Address: _____

_____

_____

Facsimile: _____

E-mail: _____

THE SEQUOIA PROJECT, INC.

NOTICE TO:

Name/Title: _____

Address: _____

_____

_____

Facsimile: _____

E-mail: _____

18.3 Governing Law, Forum, and Jurisdiction.

18.3.1 Conflicts of Law and Governing Law. In the event of a Dispute between Signatory and the RCE, the applicable federal and state conflicts of law provisions that govern the operations of the Parties shall determine governing law.

18.3.2 Jurisdiction and Venue. The RCE, currently a Virginia non-profit corporation, and Signatory each hereby submits to the exclusive jurisdiction of any state or federal court sitting in the Commonwealth of Virginia within twenty-five (25) miles of Alexandria, Virginia in any legal proceeding arising out of or relating to this Common Agreement unless otherwise required by Applicable Law. The RCE and Signatory each agrees that all claims and matters arising out of this Common Agreement may be heard and determined in such court, and each Party hereby waives any right to object to such filing on grounds of improper venue, *forum non-conveniens*, or other venue-related grounds.

18.3.3 Federal Agency Forum Selection. In the event the RCE initiates a legal proceeding arising out of or relating to this Common Agreement *and* Signatory is a U.S. federal agency, the RCE shall initiate such proceeding in a federal court, in accordance with Section 18.3.2, unless the federal courts are without jurisdiction and this requirement would act to deprive the RCE of the ability to obtain a legal remedy. The foregoing shall not preclude the federal agency Signatory from challenging the jurisdiction of such state court.

18.3.4 Participant and Subparticipant Agreements. For the avoidance of doubt, Signatory's Participant-QHIN Agreements, and the Participant's Participant-Subparticipant Agreements, as well as any Downstream Subparticipant Agreements, shall be subject to the governing law, forum, and jurisdiction provisions of those agreements.

18.4 Assignment. None of this Common Agreement, including but not limited to any of the rights created by this Common Agreement, can be transferred by either Party, whether by assignment, merger, other operation of law, change of control of the Party or otherwise, without the prior written approval of the other Party. Notwithstanding the foregoing, if ONC selects another organization to serve as the RCE, then RCE shall assign this Common Agreement to the successor RCE or an interim RCE as directed by ONC. Signatory understands and agrees that no interim or successor RCE shall have any obligation or liability for any act or omission of The Sequoia Project in connection with this Common Agreement or any of the other Framework Agreements prior to the termination of The Sequoia Project's status as the RCE.

18.5 Force Majeure. Neither Party shall be responsible for any delays or failures in performance caused by the occurrence of events or other circumstances that are beyond its reasonable control after the exercise of commercially reasonable efforts to either prevent or mitigate the effect of any such occurrence or event.

18.6 Severability. If any provision of this Common Agreement shall be adjudged by any court of competent jurisdiction to be unenforceable or invalid, that provision shall be modified to the minimum extent necessary to achieve the purpose originally intended, if possible, and the remaining provisions of this Common Agreement shall remain in full force and effect and enforceable. If such provision cannot be modified to achieve the purpose originally intended, it shall be severed from the agreement and the remaining provisions of this Common Agreement shall remain in full force and effect and enforceable.

18.7 Counterparts. This Common Agreement may be executed in one or more counterparts, each of which shall be considered an original counterpart, and shall become a binding agreement when each Party shall have executed one counterpart.

18.8 Captions. Captions appearing in this Common Agreement are for convenience only and shall not be deemed to explain, limit, or amplify the provisions of this Common Agreement.

18.9 Independent Parties. Nothing contained in this Common Agreement shall be deemed or construed as creating a joint venture or partnership between Signatory and RCE.

18.10 Acts of Contractors and Agents. To the extent that the acts or omissions of a Party's agent(s) or contractor(s), or their subcontractor(s), result in that Party's breach of and liability under this Common Agreement, said breach shall be deemed to be a breach by that Party.

18.11 Entire Agreement; Waiver. This Common Agreement, together with the QTF, SOPs, and all other attachments, exhibits, and artifacts incorporated by reference, contains the entire understanding of the Parties with regard to the subject matter contained herein. The failure of either Party to enforce, at any time, any provision of this Common Agreement shall not be construed to be a waiver of such provision, nor shall it in any way affect the validity of this Common Agreement or any part hereof or the right of such Party thereafter to enforce each and every such provision. No waiver of any breach of this Common Agreement shall be held to constitute a waiver of any other or subsequent breach, nor shall any delay by either Party to exercise any right under this Common Agreement operate as a waiver of any such right.

18.12 Effect of Agreement. Except as provided in Sections 7.4 and Section 15, nothing in this Common Agreement shall be construed to restrict either Party's right to pursue all remedies available under law for damages or other relief arising from acts or omissions of RCE or other QHINs or their Participants or Subparticipants related to the Common Agreement, or to limit any rights, immunities, or defenses to which Signatory may be entitled under Applicable Law.

18.13 Priority. In the event of any conflict or inconsistency between Applicable Law, a provision of this Common Agreement, the QTF, an SOP, and/or any implementation plans, guidance documents, or other materials or documentation the RCE makes available to QHINs, Participants, and/or Subparticipants regarding the operations or activities conducted under the Framework Agreements, the following shall be the order of precedence for this Common Agreement to the extent of such conflict or inconsistency: (1) Applicable Law; (2) this document, including Required Flow-Downs that are to be incorporated into Framework Agreements; (3) the QTF; (4) the Dispute Resolution Process, as set forth herein and further detailed in an SOP; (5) all other SOPs; (6) all other attachments, exhibits, and artifacts incorporated herein by reference, and (7) other RCE plans, documents, or materials made available regarding activities conducted under the Framework Agreements.

18.14 QHIN Time Periods. Any of the time periods relating to the Parties hereto that are specified in this Common Agreement may be changed on a case-by-case basis pursuant to the mutual written consent of the Parties, provided that these changes are not undertaken to adversely affect another QHIN and provided that these changes would not unfairly benefit either Party to the detriment of others participating in activities under the Framework Agreements. Time periods that pertain to ONC may **not** be changed, except by ONC, including the time periods for ONC review of proposed changes to the Common Agreement, the QTF, or SOPs that are set forth in Section 5.

18.15 Remedies Cumulative. The rights and remedies of the Parties provided in this Common Agreement are cumulative and are in addition to any other rights and remedies provided by Applicable Law.

18.16 Survival of Rights and Obligations. The respective rights, obligations, and liabilities of the Parties with respect to acts or omissions that occur by either Party prior to the date of expiration or termination of this Common Agreement shall survive such expiration or termination. Following any expiration or termination of this Common Agreement, the Parties shall thereafter cooperate fully and work diligently in good faith to achieve an orderly resolution of all matters resulting from such expiration or termination.

18.16.1 The following sections shall survive expiration or termination of this Common Agreement as more specifically provided below:

(i) The following sections shall survive in perpetuity following the expiration or termination of this Common Agreement: Sections 7.4 Limitation of Liability; 18.2 Notices; 18.3 Governing Law, Forum and Jurisdiction; 18.6 Severability; 18.9 Independent Parties; 18.10 Acts of Contractors and Agents; 18.11 Entire Agreement; Waiver; 18.12 Effect of Agreement; 18.13 Priority; and 18.15 Remedies Cumulative.

(ii) The following sections shall survive for a period of six (6) years following the expiration or termination of this Common Agreement: Sections 7.1 Confidential Information; 7.2.1 Statement of General Principle; 12.3 TEFCA Security Incident Notification; and 14.1 Transparency - Access to Participant-QHIN Information.

(iii) The following section shall survive for the period specifically stated in such section following the expiration or termination of this Common Agreement: Section 16.3.5 Effect of Termination of Common Agreement.

(iv) To the extent that Signatory is an IAS Provider, the provisions set forth in Section 10.6 shall survive following the termination or expiration of this Common Agreement for the respective periods set forth therein.

IN WITNESS WHEREOF, the Parties hereto, intending legally to be bound hereby, have executed and delivered this Common Agreement as of the date first above written.

RCE: THE SEQUOIA PROJECT, INC.	**Signatory:** _____
_____	_____
Signature	Signature
By: _____	By: _____
Title: _____	Title: _____
Date: _____	Date: _____

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The Trusted Exchange Framework and Common Agreement are also available on the Office of the National Coordinator for Health Information Technology's public internet website at *www.HealthIT.gov/TEFCA.*

Authority: 42 U.S.C. 300jj–11.

Suhas Tripathi,

National Coordinator for Health Information Technology.

[FR Doc. 2022–00948 Filed 1–18–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.