Consent Design Workgroup Guiding Principles

DRAFT

RESPONSE TO PUBLIC COMMENTS

Introduction

The Office of Health Strategy (OHS), guided by the Connecticut Health IT Advisory Council (HITAC), is supporting the creation of Connecticut's newly formed statewide health information exchange (HIE) entity. In coming months, the Health Information Alliance (HIA) will begin offering services to connect existing data systems and to further enable the exchange of health information between providers and healthcare organizations, and with the individuals they care for.

In preparation for the launch of HIA's data exchange services, the HITAC recommended OHS convene a Consent Design Group to develop a framework in which the state's health information technology consent policies will be approached. The Consent Design Group's work occurred over thirteen meetings from April through November of 2019.

The Consent Design Workgroup developed an extensive set of Draft Guiding Principles for OHS to use as foundational tenets for establishing future consent policies, and for evaluating technical solutions for consent management that may be offered by HIA to participants in the statewide health information exchange. The HITAC, comprised of public and private sector leaders appointed by Connecticut General Assembly leadership and by Governors Lamont and Malloy, also contributed to the draft Guiding Principles, providing a thorough review and recommending changes during several meetings between November 2019 and January 2020. The Final Report and Recommendations of the Consent Design Workgroup, contain the draft Guiding Principles as well as the background and details of the Consent Design Workgroup's process and work.

The draft Consent Guiding Principles were affirmed by the HITAC in December 2019 and reaffirmed with clarifications in January 2020. The Final Report and Recommendations of the Consent Design Workgroup details the clarifications made by the HITAC. The Guiding Principles were posted on the OHS website on February 14, 2020 along with background and a request to provide feedback by March 15, 2020. Emails were sent with background information and a request to provide input by March 15, 2020 to all OHS Listservs (450 subscribers) and to the OHS Newsletter LISTSERV (609 subscribers).

OHS received 10 public comments on the Draft Guiding Principles. These comments ranged from general support or opposition to the Guiding Principles, to specific support or opposition to one or more of the nineteen enumerated Guiding Principles. Submissions also included input not specific to the Guiding Principles.

The feedback received was assessed based on the following rubric:

1. Does the comment address a Guiding Principle?
2. If yes, does the comment address an issue regarding a Guiding Principle that was not considered during the Consent Design Group process and/or HITAC deliberations?

3. If yes, would the issue raised by the comment be best addressed by additional HITAC discussion or would the issue be better suited to consideration during the consent policy development process?
4. If no, how might HITAC and OHS ensure the comment is given consideration in the appropriate context and by the appropriate groups and/or individuals?

Each submission was analyzed against the rubric. In many cases, the Consent Design Group and HITAC meeting minutes and recordings were reviewed to answer question #2 of the rubric, with particular attention on whether the input was thoroughly vetted during the process of developing the Guiding Principles. An additional level of analysis was applied to all submissions by weighing rubric question #3, as the Guiding Principles are intended to be the beginning of consent policy development in Connecticut, not the policies themselves.

This assessment process resulted in the recommendation that HITAC affirm the Guiding Principles as written and refer the relevant feedback to OHS as the government agency charged with developing consent policies for specific purposes of data use and data exchange. This recommendation was unanimously accepted by the HITAC at its April 16, 2020 meeting.

We are grateful to the stakeholders who reviewed and submitted feedback on the Consent Guiding Principles. In reviewing the comments, a variety of themes are evident. Groups and individuals are concerned about the monetization of health information. Providers are concerned about the potential of increased administrative burden associated with implementation of consent policy. A few submissions endorsed addressing special concerns regarding historically marginalized populations, health equity, and the needs of consumers with limited English proficiency. Finally, several submitters emphasized the importance of a robust education and outreach program to ensure all Connecticut residents are informed and aware of the policies and their choice to participate in health information exchange. In all cases, we thank all who submitted feedback; your input has been shared with the HITAC and will be considered and discussed during the consent policy development process, informing the policy development work that lies ahead.

***Please note that all submissions included herein are provided in full as submitted to OHS however, formatting has not been preserved and citations have been removed. All input received can be accessed in their original form by following the links below*.**

Lesley Bennett	Stephen Smith
Dina Berlyn	Connecticut Health Policy Project
Joan Cavanagh	Connecticut Hospital Association
Supriyo B Chatterjee	Health Equity Solutions
Susan Israel, M.D.	Universal Health Care Foundation

Key Terms in this Document:

1. **ACO** – Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients.

2. **APCD** - Created in 2012 by Public Act 12-166, Connecticut's All Payer Claims Database (APCD) was established as a program to receive, store, and analyze health insurance claims data. The Act requires health insurers of health care services to submit medical and pharmacy claims data, as well as information on providers and eligibility. Information derived from this data seeks to improve the health of Connecticut's residents through the collection and analysis of data and the promotion of research addressing safety, quality, transparency, access, and efficiency at all levels of health care delivery.

3. **Binary opt-in/opt-out** – Connie (Connecticut's health Information Exchange) will assume all individuals are willing to have their health information shared through the health information exchange unless an individual chooses to officially request their health information NOT be shared through the health information exchange ("opt-out").

4. **Business Associate** - An organization providing services governed by the legal requirements for data sharing under HIPAA privacy and security rules to another organization.

5. **CDAS** - Core Data Analytic Solution – the design, development, and implementation of an innovative statewide quality measures analytics system, including electronic clinical quality measures (eCQM) and other quality analytics, in support of healthcare quality improvement activities and value-based purchasing models. The CDAS shall provide meaningful insight and analysis on transactional and clinical healthcare data and related activities in a way that supports the quadruple aim of better health, better care, lower costs, and improved work-life of healthcare providers.

6. **Consent –** An individual's statement of choices and permissions for how their health information is shared through a health information exchange.

7. **Consent management solution** – A technology system that allows individuals to electronically provide and confirm their preferences for how their protected personal and health information are shared, with their chosen preferences stored in a database for dependable usage.

8. **Consent Policy Design Group** –A group created by the Health Information Technology Advisory Council, made up of volunteer experts from the health care field, asked to research methods used across the nation and to recommend guidelines for the policies and procedures required to manage how individuals' health information is shared through the statewide health information exchange.

9. **Data security** – Protections put in place by organizations to ensure the physical, technical, and administrative safety of sensitive electronic information.

10. **Genomic medicine –** A recent area of medical practice focused on the use and understanding of human genes to improve individuals' health care.

11. **Health Information Exchange (HIE) –**
    (1) The electronic sharing of individuals' health information across other organizations within a region, community, or health system for approved uses. Electronic health information exchange allows doctors, nurses, pharmacists, and other providers to read and safely share individuals' health information, improving the speed, quality, safety, and cost of medical care.

(2) The organization created to electronically share individual health information. Connie is Connecticut's health information exchange.

12. **Participating Entity** – An entity or organization legally and technically connected to the statewide healthcare information exchange network and engaged in ongoing data exchange as defined through agreed upon use case agreements.

13. **Prescription Drug Monitoring Program** - A prescription drug monitoring program (PDMP) is an electronic database that tracks controlled substance prescriptions in a state.

14. **Trust Agreement** - The overarching legal framework that establishes a clear chain of trust regarding how health information is exchanged and a common agreement (or set of agreements) that govern transactions.

15. **Use Case** - A set of actions and sequences that govern interactions between systems and users in a particular environment and related to a particular goal to solve a problem(s) and/or provide a value proposition within the health ecosystem.

Public Comments & Responses:

1) Lesley Bennett.

I am a Stamford Resident, advocate for patients with chronic illnesses, former co-chair of the SIM Practice Transformation Task Force (PTTF) and member of the HIT-Med Rec & Polypharma committee (MRPC). While I sincerely appreciate all the hard work and vigorous discussions that members of the Design Group had before issuing this report, I am appalled that the Guiding Principles and Recommendations in this report seem to be more focused on providers and business in our state rather than on the needs of the PUBLIC and on safeguarding patients' confidential information and privacy. According to the leading Health Informatics Professional Organization (AMIA), "Patient Safety and Quality of Care are at risk if the (HIE) informed consent process does not emphasize patient comprehension." Consent for Connecticut's HIA needs to be patient-centered! In my opinion Recommendation #6 needs to be deleted from the list of recommendations and guiding principles! Recommendation #6 clearly states that" CONSENT POLICES should result in the lowest possible burden on providers responsible for their implementation and maintenance!!!! The next phrase in this principle ("...without compromising the need for sufficient patient understanding and ability to exercise meaningful consent.") does little to address the issue of what constitutes a BURDEN on the provider or what constitutes the standard a provider must meet for an effective and meaningful consent process. The process for obtaining Meaningful Consent is not an issue that can be left up to each provider or health system. Consent must be focused on the needs of patients (patient-centered) not the wants and wishes of providers, and it must be a standardized process that is fully documented in the Design Group's Recommendations and Guiding Principles. I understand (through my work on the PTTF) that many providers feel overburdened by paperwork and new duties being added to their work due to the HIE (I am willing to help advocate for more compensation to enable the hiring of more personnel). However, do Design Group members realize that professional medical (AMA) and surgical organizations are currently having problems with health care providers effectively communicating with patients to obtain meaningful

informed consent for invasive medical/surgical procedures? A recent AMA report shows that >40% of the patients who signed an informed consent for an invasive procedure did not remember or understand what they signed. In our current healthcare system, there is a great deal of pressure on providers to just obtain a patient's signature on an informed consent before a procedure. There are a number of physicians who take this process very seriously and have a very effective process for communicating with patients in order to reach a meaningful informed decision...but there are also a number of providers who rush through the process focusing only on the patient's signature and not on effectively communicating the risks/benefits of the procedure. According to AMA there are 3 major factors involved in obtaining meaningful consent: (1) Patient-related factors such as emotions, health literacy, cognitive/physical abilities, language barriers, ethnicity etc.; (2) Information-related factors such as is the info presented in electronic, written, or oral format etc.: and (3) Provider-related factors such as how well a provider communicates with a patient and understands the procedure/process. In the case of HIE, many providers in our state do not understand this system yet and are not capable of deciding what constitutes a meaningful HIE consent process. While I understand the consent process will place a time/cost burden on providers, the Design Group should not compromise PATIENT SAFETY and the Quality of Care a patient receives by making recommendation #6. Regarding Recommendations 1 and 18: at the very least I feel patients must be allowed to opt-out of the HIE. Since we are now at a time when genetic testing is being added to many patient records(and on the verge of GENOMIC Medicine being incorporated in EHRs), I would like to see the state adopt a combo opt-in and opt-out consent process similar to the one being used for the MA HIway. The Guiding Principles & Recommendations for our HIE should include a clear statement of what part of a patient's personal data can be included in the HIE without express consent, what information a patient can "opt-out" from having included in the HIE, and what information will be considered "sensitive" (such as mental health and genetic info) requiring express informed consent. Since the platform for the HIA allows for the creation of a Business Framework, I feel that the Guiding Principles must address the issue of how all this data can and will be used--for instance should it be used for research or can it be used in a "for-profit" endeavor...and if this data is used in a for-profit endeavor, how will patients be compensated? Safety of the data and what steps the HIA will take to protect the safety and confidentiality of patient data need to be clearly defined--along with a clear explanation of what constitutes patient privacy and confidential patient data. Since several of these issues may need to be addressed by statute, I feel it may be time for the HIT Advisory Council and OHS to involve members of the CGA not only in Public Hearings at the LOB and around the state on HIR consent issues but in looking at what statues that may be needed to protect confidential patient information and patient rights. I would also like to add that I believe that more "consumers" who are patients (CT residents who actually use healthcare frequently and understand/use electronic health record info and/or advocates from organizations representing those with chronic illnesses (not health policy advocates) need to be added to the HIT Advisory Council. Currently there are 5 openings on the 2020 roster listed on the public website-- 3 Chair appointees and 2 CGA appointments that I hope could be filled by patients or patient advocates.

Response to Lesley Bennett:

Thank you for raising these important concerns, which includes two distinct elements of consent. You raise concerns with respect to patients having sufficient information to meaningfully consent to medical procedures. OHS welcomes your thoughtful comments with respect to consent for procedures. We note that these guiding principles, including Recommendation No. 6, were not intended to apply to the types of procedural consents you note, but to establish parameters for engaging the public to understand how they may participate in the State's

Health Information Exchange. However, the concerns raised are important issues that will be important to future discussions about meaningful and informed patient consent. The other context for consent in your comments pertains to sharing health data that is the intended target of these guiding principles. In this regard, your comments raise considerations that will have to be addressed and balanced against concerns raised regarding those responsible for administering this type of consent. OHS commits to further discussion on this topic that brings together the viewpoints of both sides of this issue. . OHS will develop an educational campaign that includes patients and consumers in the design process. That educational campaign will be broadcast widely in Connecticut. We appreciate your insights about the important issue of patient opt-out and opt-in. OHS is adopting an opt-out consent model, similar to that used by the Mass HIway (the Massachusetts statewide HIE) and the majority of other states. In this model, a patient's basic clinical data is available within the HIE unless a patient opts-out of participating in the HIE. However, pursuant to state and federal law, a patient's sensitive or protected data cannot be shared within the HIE unless a patient expressly agrees to opt-in, allowing that data to also be accessible in the HIE. Finally, your additional observation regarding adding patients or representatives of patients with chronic conditions who are knowledgeable about health data to the HITAC. During the April 2020 Council meeting, the members affirmed a charter that set forth procedures for nominating candidates to fill vacancies, among other things. Your comment has been shared with the Co-chairs of the Council and solicitation for consumer representation on the HITAC will be forthcoming.

2) **Dina Berlyn**.

I am extremely concerned by an article a couple of weeks ago that appeared to indicate that insurers would have direct/ unfettered access to patient data in the HIE. I do not believe that the statutory language allows this, and I know that that was not the intent of the drafters. The HIE is for #1 the patients and #2 the providers. It was never intended to be some kind of bonanza for the insurers.

Response to Dina Berlyn:

Health insurers will not have direct, unfettered access to any data in the HIE. Any disclosure of health information, to any party, must be done so in a manner that is consistent with federal and state statutes and regulations governing health information. Existing law allows such disclosure to insurers for the purposes of payment, treatment, and healthcare operations, within the constraints of existing legal relationships between the parties, which is established as Participating Organizations execute the legal trust agreements with HIA and establish the required Business Associate relationships between the parties. These agreements will govern all access to and use of health information, so any request for the protected health information must be consistent with these legal requirements. As established in Conn. Gen. Stat. 17b-59d(b), the purpose of the HIE is to, in relevant part: 1) Allow real-time, secure access to patient health information and complete medical records across all health care provider settings; 2) provide patients with secure electronic access to their health information; 3) allow voluntary participation by patients to access their health information at no cost; 4) support care coordination through real-time alerts and timely access to clinical information; 5) reduce costs associated with preventable readmissions, duplicative testing and medical errors; 6) promote the highest level of interoperability; 7) meet all state and federal privacy and security requirements; 8) support public health reporting, quality improvement, academic research and health care delivery and payment reform through data aggregation and analytics. Connecticut's HIE has been designed to facilitate the realization of these important statutory objectives. Importantly, we note that the HIE will not hold the patient information as part of routine operations. Instead, the HIE follows a federated data governance model, where each Participating Organization's data resides in its Electronic Health Record system, but is indexed at the HIE level to facilitate the compliance with the statutory requirements. Certain Use

Cases, agreed upon in advance by all Participating Organizations that choose to participate, may necessitate that some data be temporarily stored in the HIE, for the narrow purposes set forth in the Use Case.

3) **Joan Cavanaugh.**

I am concerned about the Health Information Exchange to be implemented by the Office of Health Strategy in Connecticut. Such a system must include a policy enabling individual patient consent regarding what parts of our personal medical data may be shared, and with whom. We must be able to see any data that is being provided. Through widespread and accessible public education, patients need to be fully informed about both the risks and the benefits involved in permitting the sharing of any information. In addition, there must be an explicit, legally binding commitment that medical data will never be shared with insurance companies or other insurance providers. Without these guarantees, there is great danger of health care rationing and discrimination against certain patients for a myriad of reasons. Two of the most serious public health issues today are a growing lack of confidence in the health care system and its lack of accessibility to the most vulnerable among us. Please ensure that any new measures are designed to improve, not exacerbate, these problems.

Response to Joan Cavanaugh:

Thank you so much for your comment and sharing your concerns. OHS recognizes the need to ensure consumer/patient privacy rights and preferences are safeguarded. OHS is working to develop a consent management solution that will empower patients to express their consent preferences, allowing each person to take individual control of their data and specify which providers will be able to access what information. We also recognize the need for accessible public outreach and education about this important State initiative and are reviewing strategies to better inform the public on how their data can be accessed and utilized for their treatment. Given that a final, comprehensive consent management solution has not yet been developed or selected, capabilities will be commenced at this time to permit sharing of information among and between patients and providers, for which patients will have the opportunity to opt-out of having their data shared across the HIA platform. This option will be all data in or all out. As functionality for sharing among a wider group of participating entities (agencies, providers) and use cases expands (e.g., research, health policy, etc.), patients will be afforded an opportunity to modify their degree of participation, if so desired. Insurers will be required to adhere to federal and state statutes and regulations governing health information which currently allow insurers access to health information solely for the purposes of payment, treatment, and healthcare operations. The specific consent policies and HIA legal agreements will govern insurers', as well as any other health information exchange participant's, access to and use of health information. Such use is consistent with current HIEs operating across the country. Use of health information for discriminatory purposes is prohibited under state and federal law. OHS will develop a complaint process so that patients will be able to express and address their concerns.

4) **Supriyo B. Chatterjee.**

I would like to thank you for this opportunity to provide a public comment on the Office of Health Strategy's (OHS) proposed Draft Guiding Principles in the Final Report and Recommendations put together by the Consent Design Workgroup. I am in the healthcare policy and information technology (HIT) sector for economic development in Connecticut. I work with small startup businesses, major corporations, hospitals, non-profits, and academic institutions (UConn & Yale Universities). I am part of the State

Innovation Model (SIM) program in the Practice Transformation Task Force (PTTF) group. I am also a Connecticut Health Foundation Healthcare Leadership Fellow.

I seek further elaboration of certain points below in the management of the State Health Information Exchange (HIE) as stated in the Final Report and Recommendations.

New Rulings from US Dept of Health & Human Services (HHS)
On March 9, 2020 HHS released transformative rulings that further empowers the patient consumer over their healthcare records. This "will give patients unprecedented safe, secure access to their health data. Interoperability has been pursued by multiple administrations and numerous laws, and today, these rules finally deliver on giving patients true access to their healthcare data to make informed healthcare decisions and better manage their care." How will the Guiding Principles address this recent ruling? What will be the default setting for patient participation – 'opt-in' or 'opt-out'? This applies to 'Recommendation 1, 8, 9, and 16' of the Guiding Principles.

The new HHS Interoperability and Patient Access final rule (CMS-9115-F) has several other items that will need to be considered: Patient Access API, Provider Directory API, Payer-to-Payer Data Exchange, Dual Eligibility Data Exchanges, Public Reporting and Information Blocking, Digital Contact Information, and ADT (Admission, Discharge, and Transfer Events) Notifications. How will the Guiding Principles address these items? This applies to 'Recommendations 4, 5, 11, 12, and 13' of the Guiding Principles.

Privacy and Health Equity
While the new HHS Interoperability and Patient Access final rule (CMS-9115-F) provides the patient consumer the benefit of organizing their healthcare and related data – the matter of privacy of the data is unclear. How will the Guiding Principles address the privacy concerns? This applies to 'Recommendations 5, 11, 12, and 13' of the Guiding Principles.

Utilization and Monetization
As the patient consumer data will be managed by various vendors and institutions – it gives them the opportunity of utilization and monetization of patient consumer data. How will the Guiding Principles address the concern of utilization and monetization of the patient consumer data? Can the patient consumer completely opt-out of the utilization and monetization of their data? This applies to 'Recommendations 5, 7, 8, 10, 11, 12, 13, 18, and 19' of the Guiding Principles.

Response to Supriyo B. Chatterjee:

Thank you for your thoughtful insights and important questions about how the Consent Design Guiding Principles will incorporate recent policy changes from the U.S. Dept. Of Health and Human Services. Consent policy is required to conform with all existing federal and state laws and regulations, as well as emerging laws and regulations such as the Information Blocking Rule. OHS has a process established for proposed policies. A proposed policy or procedure goes into effect at the time it is submitted into the State's regulatory process, and remains in effect until such time as the regulatory process plays out, makes changes, or as happens in certain cases, enough time goes by that the agency itself comes back and resubmits modifications to the policy. While the Guiding Principles do not govern OHS' regulatory process, they establish baseline policy considerations that OHS must consider and incorporate into the draft regulations, with the focus on concerns expressed regarding privacy, consistent with federal and state policies. As the HIE builds its technical capabilities, a robust consent

management solution will be identified that expands patient options for managing access to their personal health information (PHI). The initial consent model will provide patients with an opportunity to opt-out of participating in the HIE in any capacity. This "in or out" model recognizes the challenges implicit in this area, giving patients control over their PHI while promoting ongoing development of the HIE's capabilities. As soon as feasible, the HIE will implement a robust consent management model that provides patients with a simple, intuitive interface through which to manage permissions to their PHI in a very granular manner, including decisions about specific provider access and control over specific, sometimes specially protected, PHI. However, to restate a critically important, fundamental concept - once the HIE begins exchanging data, the patient will always have the opportunity to opt-out during anytime from having their health records shared in the HIE. The ability to opt-out will remain in place until the electronic consent management system is implemented. The Privacy Work Group, one of the five workgroups operating under the Health Information Alliance, Inc. Operations Advisory Committee, will consider consent implications as each use case is developed (consistent with Guiding Principles). Once more comprehensive consent policies are developed and a more robust consent management solution is developed/selected, consumers will be offered the opportunity to revise consent decisions. OHS will conduct outreach and provide educational resources for consumers so that they are able to make informed decisions. Regarding the concern of utilization and monetization of patient consumer data, the CT health information exchange has no intention of selling patient data. The patient data will be utilized so that health care providers are able to see the same information about a shared patient that could help improve care coordination and quality and reduce duplicative tests. Additionally, the data being exchanged between providers will be used to analyze patient experiences to identify health outcomes, and population health trends.

5) **Susan Israel**.

Thank you very much for this opportunity to give further comment for a wider regulatory process. The Guiding Principles are fine in themselves for the overall exchange processes, but they do not specifically address, nor ask for comments on, the most crucial issue of moving medical data, which is the consent of the patient to do so. Any such discussion occurs in the Additional Considerations which are outside the body of the report. Thus, it remains unclear whether or not OHS will allow patients to control who can see their medical data and records or even be informed of all those who can access them.

Hopefully, there will be an opt-in (preferably) or an opt-out system installed in the Health Information Alliance so that no medical data will be moved into or through it without the express consent of the patient. Patient identifiers and provider matching lists must be a "use case" that requires consent, not entered automatically. This would follow the original HIE legislation for patients to list their providers, not for their providers list their names with the State of CT through the HIA.

Likewise, no medical records, including Clinical Care Summaries and Admission/Discharge/Transfers, etc., would be transferred through or into the exchange without the specific permission of the patient. This express consent of the patient could not be supplanted by any implied consent from just engaging in medical care where, without further consent and knowledge according to HIPAA since 2003, there can be the sharing of data between providers (covered entities) and their business associates for treatment, payment and health care operations.

The mandated, identified medical data sent by providers to the OHS and the Department of Public Health (DPH) must require patient consent to be moved through any exchange or any system where business associates will see their identified data. The method of movement and handling of these identified, intimate data must be transparent to citizens, because they include infectious diseases, outpatient surgical and inpatient discharge summaries, tumor registry data, quality control metrics, CDAS and the All Payer Claims (health insurance) Data (APCD).

A discussion of the State of CT and medical data must include the HIA's consideration to include the Prescription Drug Monitoring Program, which besides opioids, includes some psychiatric medications, with the name of the prescribing provider and the date. This identified information is entered into a centralized data base to which many have access: business associates, providers, pharmacists, state oversight, law enforcement, and even other states. It does follow the HIPAA rules for confidentiality, but this is not what most people would consider privacy to be. Additionally, the HIA may incorporate a centralized data base which will include all a patient's medications. But will this data base be created with or without the patient's express consent? Or will providers, pharmacies and business associates be allowed to share one's medications in such an expansive way, without further consent just because one engaged in treatment? Hopefully, the Office of Health Strategy, through the creation of the HIA, will become a proponent of patient consent.

Response to Susan Israel:

Thank you for sharing your views on the issue of opt-out versus opt-in. OHS intends to pursue an opt-out consent model similar to the majority of other states. This model will be subject to the transparency and inclusiveness inherent in the State's regulatory processes. Under this model, patients whose providers have connected to the HIE, as they are required to by state law, will have their basic clinical data included in the HIE automatically. However, consistent with the law, sensitive or protected data (e.g. mental health or substance use data), requires express, specific *opt-in* consent from each patient, and will not be accessible in the HIE without this specific, patient-directed, consent. Further, only providers who have necessary legal relationships with the HIE or other providers may share their patients' data. This conforms with applicable law, including HIPAA regulations for Covered Entities and their Business Associates. These comments raise considerations that will have to be addressed and balanced against concerns raised from those responsible for administering privacy practices in health care organizations. OHS commits to take your comments into consideration as it proceeds with its regulatory processes. OHS welcomes your thoughts on patient and provider identifiers and will consider those comments as it proceeds through the regulatory processes. OHS acknowledges your concerns related to gathering personal health information for mandatory public health or other lawful purposes. The state routinely engages third parties to perform necessary functions in pursuit of agency missions. The All Payer Claims Data Base, Prescription Drug Monitoring Program and disease surveillance needs that you reference are three of many such examples. The use of third parties is an important means to deliver robust and efficient services to the state and are governed by clear contractual expectations for privacy and security. Such services are not subject to patient consent. OHS agrees that clarity on uses of data is vital to transparency and the ultimate success of the HIE. In the likely event that HIA is contracted by a state agency to process health data for a lawful purpose, OHS will take your comments into consideration with respect to disclosure and educational information that provides clarity as it pursues its regulatory processes. Your questions above refer to consent for sharing data. OHS believes meaningful patient choice is essential to the success of health information exchange in the state and will pursue

the consent model described above. OHS will develop an educational campaign that includes patients and consumers in the design process. That educational campaign will be broadcast widely in Connecticut.

6) **Stephen Smith**.
The guidelines appear well thought out. Recommendation 17 is awkwardly worded. Inserting "that" after "require" would help.

Response to Stephen Smith:

Thank you for your taking the time to review the Consent Design Draft Guiding Principles. Currently OHS is seeking feedback on the content of the recommendations to help inform future planning for consent policies. However, the input you provided (insert "that" after "require") will be considered as we begin to implement stylistic changes to the Guiding Principles.

7) **Connecticut Health Policy Project**.
Thank you for this opportunity to provide comment on the Office of Health Strategy's (OHS) proposed guiding principles on the Final Report and Recommendations of the Consent Design Workgroup. I listened in on some of the online meetings of the workgroup. For twenty years, the CT Health Policy Project, a nonpartisan nonprofit consumer advocacy organization, has worked to expand access to quality care for every state resident. We have several concerns with OHS's process and development of a state Health Information Exchange (HIE). We are especially concerned about plans to sell/monetize consumers' medical records and data to insurers and Accountable Care Organizations (ACOs) with strong incentives to lower the cost of our care. There is considerable concern, supported up by evidence in the literature, that cost reduction by these entities can be generated by cherry-picking patients and by withholding necessary care.

HIE to connect individual healthcare providers caring for individual patients, with the patient's fully informed consent, can both improve care and reduce costs. But allowing HIE access to insurers, ACOs, or any entity with financial incentives to deny care is unacceptable and further undermines already low levels of public trust in the healthcare system and state government.

It is not clear that the state's plans for an HIE adds value to what already exists in our state. Seventy percent of Connecticut hospitals and 57% of doctors now share clinical information between health systems, rates above the national average. There are at least four functional HIEs operating in Connecticut now, with no taxpayer support. Any potential value of the state's additional HIE is certainly not worth the risk to people's care and eroding already low levels of public trust in the healthcare system.

The news is full of scandals and concerns about large entities selling our data without our consent or knowledge. Medical records are far more sensitive than browsing history or survey responses. Getting HIE privacy controls wrong risks discrimination, embarrassment, and worse for consumers. The absence of consumer controls will likely keep some people from getting necessary care, with serious consequences.

We are concerned that our private information will be in the HIE system and risky funding decisions will be made before a protective consent policy guaranteeing privacy and consumer control over our information are established. Funding needs when federal support is exhausted should not be a justification for ignoring consumer rights. We urge you to develop, with proper public input, a consumer-directed

consent policy with a robust public education effort to ensure decisions are informed. To build public trust, that process must be completely independent of and not controlled by OHS, the Health IT Advisory Council, or HIA, contrary to Recommendations #2, #3 and #19. The state has a terrible record of informing consumers of their rights. In Connecticut Medicaid's development of the PCMH Plus program, built on provider financial risk for the total cost of care, required client notices were altered to remove description of patients' risks.

A consent policy that requires consumers to choose between getting needed healthcare and risking their privacy is unconscionable. As providers will be required under state law to participate in the HIE, this is a very real concern.

The process of developing the guidelines, and the entire process to develop the state Health Information Exchange (HIE) are troubling. OHS's workgroup meetings on consent were held online with minimal public notice. The consumer advocate on the consent workgroup was treated disrespectfully despite having a deep knowledge of HIEs and privacy/security issues. When it became clear that the workgroup could not come to consensus on a policy, it was decided to end with vague guiding principles.

In a very unusual decision, the HIE is being developed through a nonprofit, Health Information Alliance Inc. (HIA), to run the HIE with millions of tax dollars rather than a governmental entity subject to transparency and bound by public constraints about the use of consumers' medical records. HIA's Board of Directors includes insurers and large health systems that expect to have access to our personal information. HIA's Board meets evenings in a conference room in Farmington.

We urge you to immediately commit that consumers' personal health and medical information will never be sold/monetized or shared with insurers, ACOs or any entity with financial risk. We also urge you to halt entry of any patient information into the HIE until a fair consent policy is developed giving consumers control over who sees their medical information and preserves choice.

Response to the Connecticut Health Policy Project:

Thank you for your comments and perspective about Connecticut's Consent Design process. You've raised several important issues in this discussion, and we appreciate the opportunity to address these concerns.

With respect to your input regarding insurers and ACOs, they, as do all Participating Organizations (organizations, which may include insurers, that have executed the legal trust agreement with HIA), will be required to abide by the federal and state laws and regulations governing the protection of patient health information. As you may know, current law allows payers and other providers access to health information for the purposes of payment, treatment, and healthcare operations, so long as the necessary legal relationships have been established. The specific consent policies will govern Participating Organization's access to and use of health information through the HIE, ensuring it is shared solely in strict compliance with state and federal law and regulations, consistent with the legal trust agreements and, most importantly, that patients are provided with meaningful, equitable and timely information about their options. In line with Guiding Principle 8, a consent management solution will be identified and implemented and, when complete, will provide patients with a high level of granularity when selecting their consent preferences. This will include provider and, as applicable, specific circumstances for patients to select who they wish to have access to which parts of their medical record. Consistent with the Consent Design Group's recommendations, work to identify and implement a comprehensive consent management

solution is underway. This will likely be implemented in stages, as more Participating Organizations complete the HIE's Onboarding process, with the first step being the development of a binary opt-in/opt-out process for patients of the first wave of Participating Organizations. As the HIE continues to implement its operational plan, additional and more granular patient options will be rolled out, consistent with OHS and the State's commitment to patient choice. As functionality for sharing among a wider group of participating entities and use cases expands (e.g., research, health policy, etc.), patients will be afforded an opportunity to decide on their degree of participation, if so desired. Consistent with Guiding Principles 2, 3, and 6, OHS is committed to and actively working on developing effective consumer outreach and education plans. OHS adheres to the principle that patients must have enough understanding about what this means to them, what the pros and cons may be, to make an informed choice about consent. Information must be widely available to patients, providers, and other stakeholders about the opportunity for patients to opt-out of data being exchanged across the HIE during this interim time period until the consent management solution is in place, as well as continuing development and implementation of this policy. In furtherance of this goal, we are actively engaged with other states that have already implemented an HIE to gain additional insight about what they've done as we develop a robust consumer engagement process to run in parallel with the regulatory process, with all of its transparency, as well as develop tools/processes to promote maximum consumer engagement, education and understanding. Regarding your concern about the HIE being a non-profit entity, many HIEs across the nation have been developed utilizing this same public-private partnership model. OHS will continue to look at best practices for consent management as this is a rapidly evolved workspace, especially in light of the unprecedented challenges posed by the COVID-19 crisis. Once OHS completes drafting the initial consent policy, the draft regulations will be subject to the State's regulatory process. In addition to the robust transparency and public input that the regulatory process promotes, OHS is also developing a comprehensive consumer outreach and engagement plan. When fully developed, the draft consent regulations will be shared publicly, and an open comment period will be required to allow for comment on each specific policy prior to the final approval of the policy.

8) Connecticut Hospital Association (CHA).

It is evident that the Consent Policy Design Group engaged in thoughtful and wide-ranging discussions to inform and create the draft Guiding Principles and recommendations in the Final Report. We are grateful to them for their efforts and appreciate the hours of work and care the Design Group members, staff, and consultants dedicated to creating the work product. CHA appreciates the opportunity to comment on the Final Report and looks forward to working with OHS and the Health IT Advisory Council as they develop and finalize the consent process.

Our comments separately address each of the 19 recommendations set forth in the Final Report. We included the text of each recommendation below, in italics, for easy reference.

Recommendation 1: Consent policies should require patients be provided clear and detailed information about health information sharing choices under applicable State and Federal law.

CHA comment: We support consumers receiving clear, uniform, practical choices for how their information may be shared through the statewide health information exchange (State HIE).

We urge that the State HIE materials be particularly clear about information sharing choices; specifically, that such choices affect only data exchanged by and through the State HIE. Even if a patient opts out of the State HIE, data will continue to be exchanged outside of the State HIE process, for myriad permitted purposes. Unless this is very clear, there is substantial risk of confusing consumers.

Further, if the State HIE intends to collect and retain data apart from provider-to-provider or provider-to-patient uses, that intention should be made obvious to and understandable by patients, and should include a well-defined listing or description of the various uses the state will have for the data. While an underlying principle for the consent process is to follow HIPAA, patients should be advised that HIPAA rules often will no longer apply to data once in the hands of the state.

Many state agencies are neither HIPAA covered entities nor HIPAA business associates. DSS is a significant exception because DSS is a HIPAA covered entity as a healthcare payer program. Conversely, most state agencies have no HIPAA obligations controlling data use or data release, unless those obligations are created by Connecticut statute. While it makes sense to explain to patients that hospitals and other providers are permitted to provide the state with data pursuant to various HIPAA sharing rules, it would be misleading to infer that those data are necessarily HIPAA protected once they are in the state's control.

Consider that, with very few exceptions, a HIPAA business associate must take instruction from a covered entity as to any limitations on use of data received from the covered entity. A business associate must return or destroy data from a covered entity (with limited exceptions) when the covered entity instructs, or when the relationship ends. Data that are collected by the state are no longer subject to directives from the covered entity that sent the data. In addition, after the state collects the data, the state has no HIPAA obligation to: (1) stop using the data; (2) return or destroy the data; or (3) inform patients of continued uses of their data. A meaningful consent process should include detailed explanations of these differences when patient information becomes state collected data.

Response to CHA: Your input on this topic is insightful and welcome and OHS is committed in the regulatory process to ensuring clarity on the topics you raised to avoid the consumer concerns you identify herein.

Recommendation 2: Consent policies should require Connecticut's Office of Health Strategy to develop an educational resource tool kit on health information sharing, leveraging and adapting content from recognized third party resources.

CHA comment: All educational materials should be centrally and uniformly sourced by the state, including providing the expectations for how the materials are to be distributed.

Explaining that the HIE will advance the ability of providers to share data with each other and with patients is important, but even more essential is building trust with consumers and patients by being openly transparent about other uses, including how the state will use the data.

To ensure that consumers have a full and transparent understanding of why they are being asked to share their data with the State HIE, the state's role in the HIE should be fully explained, including that the state is mandating hospital and provider participation in the State HIE, and that the state (and others) will utilize consumer data for various projects and purposes.

Response to CHA: Your input has been shared with OHS and the HITAC and will be considered and discussed during the consent policy development process. OHS will follow the statute and work to fully explain the state's role in regard to the HIE and the impacts and enhancements throughout the state's healthcare ecosystem.

Recommendation 3: Information and educational resources on consent policies should be distributed broadly throughout Connecticut and be made widely available and easily accessible through a variety of sources including the Health Information Alliance, all health and human services agencies and departments in the state of Connecticut, and organizations participating in HIE services in Connecticut. The distribution process will be supported by HIA's partners, including the Office of Health Strategy (OHS).

CHA comment: We support wide distribution of educational resources that are developed and approved by the state. For clarity, the Office of Health Strategy is not merely a partner of the HIA (as inferred in Recommendation 3). By law, OHS retains administrative authority for the State HIE, which includes the HIA. OHS, not the HIA, should make decisions about the patient consent process, and educational materials describing consent for the State HIE, consistent with regulatory rule-making requirements and administrative procedures (as discussed in Recommendation 19).

Response to CHA: OHS agrees with your input. OHS is responsible by statue and recognizes that, in keeping with the statute that the HIE must be developed as a neutral and trusted entity.

Recommendation 4: A review of consent policy considerations should be conducted for each HIE use case before an HIE use case is put into production, with a use case-specific consent policy developed if indicated from the review.

CHA comment: We agree that, before a use case goes into production, recognizing what patient and consumer consents may be needed is important. We strongly caution, however, that obtaining reconsent from patients and consumers for each new use case is infeasible. Other than at point of service, which does not occur frequently for most patients, obtaining written feedback or a patient's affirmative consent is difficult.

Additionally, patients should be informed that data that is incorporated into a provider's records or carrier's records will not be removed even if the patient opts out of continued participation in the State HIE.

Response to CHA: Your comments raise considerations that will have to be addressed in detail and balanced against concerns raised regarding the desire to develop use case consent. OHS commits to further discussion on this topic that brings together the viewpoints of both sides of this issue.

Recommendation 5: Notification of a healthcare organization's participation in electronic health information exchange(s) should be included in the Notices of Privacy Practices (NPP).

CHA comment: We disagree with this principle if, and to the extent, it is intended to require providers or carriers to amend their HIPAA Notice of Privacy Practices (NPP) to specifically identify the State HIE. Patient consent forms or educational materials, or notices if needed, created by the state, should provide that information. Requiring amendments to existing NPPs is an unnecessary step that will create cost and administrative burdens for providers.

Response to CHA: OHS acknowledges your input, further noting that your point on provider burden relates directly to Recommendation 6 below. OHS agrees that patient education is a vital part of ensuring the success of health information exchange in CT and commits to take this feedback into consideration.

Recommendation 6: Consent policies should result in the lowest possible burden on providers responsible for their implementation and maintenance, without compromising the need for sufficient patient understanding and ability to exercise meaningful consent.

CHA comment: We support this principle. The State HIE should develop a uniform consent process with associated consent management tools that are user-friendly for providers and patients, and that do not require providers and carriers to create unnecessary steps or internal processes to capture consent or to document notice of HIE participation.

Response: OHS agrees with your feedback. This is essential, as OHS does not want to create additional or undue burden on providers, patients and carriers.

Recommendation 7: Clearly written information about consent policy changes should be provided to patients, parents and guardians, state and local health and human service agencies, and all licensed healthcare entities in a timely manner when policies or practices have changed, adhering to the principles of broad dissemination and accessibility of information described above.

CHA comment: We support this principle. We caution that changes in policy will be difficult to administer with previously obtained consents.

Response to CHA: OHS agrees with the cautionary point you raise and acknowledges that the implications to previously obtained patient consents must be considered as an integral part of any proposed policy change process.

Recommendation 8: Mechanisms, including paper based and digital tools, for expressing consent policy preferences should be user-friendly and easily accessible.

CHA comment: For the mechanisms used for expressing consent, we support ease of use for providers, carriers, and patients. We caution that expectations for managing consents (including retention, linking to patient and consumer records, and security for digital versions) should be given careful consideration to ensure that State HIE participants are able to comply using existing systems and tools, and to avoid creating added costs or administrative burdens.

Response to CHA: OHS agrees with the cautionary point you raise and commits to ensuring a process for obtaining input from HIE participating organizations, patients and others are included in the design of consent capture mechanisms.

Recommendation 9: Consent policies should explain clearly and completely what happens if a patient revokes consent, including what happens with patient data and their previously expressed consent.

CHA comment: We support clear messaging to patients and consumers about consent and revocation of consent. The recommendation for the State HIE is for an opt out process. The term “revocation” may not

adequately describe the process of opting out because the initial consent would be passive consent (subject to a future opt out). As stated above, it is critical to convey that a revocation (or opt out) of the State HIE does not affect other data sharing that is outside of the State HIE, or continued use of data by certain state agencies or providers that have integrated the data into their systems.

We urge specific, clear communication be included in educational materials about state mandated health data reporting systems, for which patients have no consent rights or ability to opt out. This would include, for example, the Connecticut Prescription Monitoring and Reporting System (often called the PDMP), or communicable disease reporting to DPH. The recent, media-covered episode of a family that professed significant confusion and disagreement (which eventually became the basis for a lawsuit against the state) about how, in that case, DPH collects, uses, and shares immunization data, provides a clear example of why communication about how the State HIE will collect, use, and share data should be comprehensive and transparent.

We also urge careful consideration be given to the differences between passive consent (or opt out) versus fact patterns (or use cases) that would require a HIPAA-compliant authorization pursuant to 45 CFR 164.508. Because the State HIE use cases are not yet known, it is not obvious whether some use cases might require a HIPAA-compliant authorization. A HIPAA-compliant authorization must utilize specific revocation language, per HIPAA rules.

Response to CHA: Thank you for raising the need to clarify the difference between revocation and opt-out. We agree with the need for clear communication and education. OHS agrees to ensure clarity on passive consent versus use cases that require a HIPAA compliant authorization.

Recommendation 10: Third-party vendors and contractors supporting HIA, Inc. in its health information exchange activities should be contractually bound by HIA, Inc. to abide by the consent policies of HIA, Inc.

CHA comment: We have one comment and one question about recommendation 10.

Comment: We agree that vendors and contractors should be aware of, and agree to comply with, applicable consent policies set by the State HIE. This presupposes that all policies are consistent with state and federal law, including HIPAA. Pursuant to HIPAA regulations, the HIE is necessarily the business associate of the covered entities that supply PHI to the HIE. Those covered entities, by law, will not be the business associates of the HIA or the State HIE. The State HIE is not a covered entity, but as a business associate, the HIE has an obligation to require vendors that may be exposed to PHI to be its (subcontractor) business associates, as part of the contracting process.

Response to CHA: Thank you for this explanation. OHS understands and agrees with your comment.

Question: To what extent will third-party vendors and contractors supporting HIA Inc. be required and/or expected to follow (i) state contracting rules and (ii) state ethics rules in light of the fact that the HIA is "acting on behalf of the state." Conn. Gen. Stat. § 17b-59a. The form and format of the terms of required business associate contracts may be affected by these rules.

Response to CHA: HIA operates under a conflict of interest policy that balances the needs inherent in a nongovernmental entity that performs work on behalf of the state. This policy was drafted and agreed by the Office or Policy and Management (OPM) and OHS. The HIA board adopted a procurement policy that aligns with the Federal Office of Management and Budget (OMB) micro-finance procurement guidelines for nonprofits, with the addition of requiring certification for non-discrimination for contracts above $50K, and certification of gift policies for contracts over $500K that are required under State procurement rules.

Recommendation 11: Consistent with federal and state law, including but not limited to HIPAA, consent policies should require safeguards be followed consistent with the responsible stewardship associated with protection of a patient's health information against risks such as loss or unauthorized access, use, alteration, destruction, unauthorized annotation, or disclosure.

CHA comment: Hospitals are HIPAA covered entities, and their data are protected and handled consistent with HIPAA rules and regulations. Requiring safeguards that providers already must follow pursuant to federal law is redundant and does not increase privacy or security of the data.

Further, entities that participate in the State HIE that are not covered entities or business associates cannot be transformed into HIPAA entities by contract or state policy, but they can be asked to follow similar safeguards. It is critically important to HIPAA compliance for all participants to know which entities are required to follow HIPAA, and which are not. The rules for exchanging data between HIPAA covered entities differ (sometimes dramatically) from the rules for sharing outside of HIPAA regulated entities. The consent policies should reflect and explain each of these legally defined and regulated roles.

Similarly, the varied roles of the State HIE and the state should be clarified in consent policies and consent materials. As discussed above, many state agencies that likely will have access to data from the HIE are not bound by HIPAA pursuant to federal law.

Response to CHA: Thank you drawing attention to the differences between organizations regulated by HIPAA and those that are not, including State agencies. OHS is committed in the regulatory process to ensuring clarity on the differences between these types of participating organizations.

Recommendation 12 Consent policies shall address sensitive and specially protected data in alignment with federal and state statutes, as may change from time to time.

CHA comment: We urge careful consideration of consent and authorization issues presented by specially protected and sensitive data. Which data can be exchanged through passive consent (opt out or through a notice) is significantly distinct from fact patterns (or use cases) that would require a HIPAA compliant authorization pursuant to 45 CFR 164.508, or additional, specific written consent pursuant to 42 CFR part 2 (the federal rules that control substance use disorder confidentiality).

Response to CHA: Thank you for calling attention to the needs surrounding sensitive data. OHS is committed in the regulatory process to ensuring clarity on the topics you raised.

Recommendation 13: Consent policies should be aligned with certain national interoperability initiatives, including the Common Agreement (CA) under development as part of Trusted Exchange Framework and Common Agreement (TEFCA), to support the ability to exchange data with entities outside the state.

CHA comment: We support this concept and agree that the State HIE must follow all mandated federal interoperability standards. But we caution that adopting optional requirements should only be done after careful consideration of the capability of providers and others to comply without added costs or burden.

Response to CHA: Thank you for reminding us of possible impacts on providers and costs. OHS will take the point you raise into consideration as it proceeds through its regulatory process. OHS will consider engaging with providers on any optional requirements to determine the impact such requirements could put on providers and others.

Recommendation 14: Consent policies should be reviewed periodically to ensure it is aligned with these principles and complies with any changes in best practices or federal or state law.

CHA comment: We support this concept but caution that substantive changes should be made only when necessary because changes to the consent policy or process will cause disruption for data capture and increase operational expenses for the State HIE and participants.

Response to CHA: OHS agrees with the cautionary point you raise and commits that the implications to provider burdens and costs will be considered for any proposed policy changes. OHS does not want to create disruptions for data capture or increase operational expenses and will be keenly aware of how periodic updates and alignment should be carefully thought and planned out.

Recommendation 15: Consent policies should provide a clear procedure for addressing complaints by individuals regarding the use of their data.

CHA comment: We support having a complaint process for consumers, but that process must recognize that covered entities cannot delegate or avoid their federal obligations under the HIPAA breach notification rules set forth in 45 CFR 164.400-414. Any process concerning a complaint that may relate to breach or the need to conduct a breach investigation must be fully aligned with those federal rules.

Additionally, hospitals have an obligation, pursuant to the Medicare Conditions of Participation, to evaluate and respond to all patient complaints. The State HIE should be required to inform hospitals as soon as possible about any patient complaint involving a hospital participant.

Response to CHA: OHS agrees with your comment and is committed to ensuring the policies it develops during the regulatory process is compatible with Federal regulations as well as a complaint process for patients.

Recommendation 16: Consent policies should require that patients have ample opportunity to review educational material before making a consent decision.

CHA comment: We support this principle. We caution that implementing a process that requires express feedback from patients other than at point of care is difficult. Patients will be at point of care only episodically, and for many patients, infrequently.

Response to CHA: Thank you for raising this point. This is true for many patients and OHS will engage with patients and stakeholders to review educational materials so that the point of care is not the only exposure. OHS will take this practical consideration into account as it proceeds with its regulatory processes.

Recommendation 17: Consent policies should require a consent decision is not used for discriminatory purposes.

CHA comment: We support this principle. While not discriminatory, patients should be told that there will be times that a decision to opt out of participation might affect how organizations, agencies, and other providers can assist them.

Response to CHA: Thank you for raising this welcome consideration. OHS will work to determine clear ways to make patients aware that decisions to opt out could impact how providers can assist them. OHS is committed to ensuring patients understand the implications you raise as it develops its regulatory processes.

Recommendation 18: Assessments should be made periodically to ensure patients understand their health information sharing choices.

CHA comment: We support this principle. We urge that assessments be designed in a way that creates little or no burden for providers and patients. Consistent with our earlier comments, we caution that implementing a process that requires express feedback from patients other than at point of care is difficult. Patients will be at point of care only episodically, and for many patients, infrequently.

Response to CHA: Thank you for raising another important consideration. OHS believes that a consent management solution that is being developed could be utilized for patients to express their consent choices, and periodically revisit their health information sharing choices without creating and undo burden on providers or patients. As above, OHS commits to take these practical concerns into consideration as it proceeds with its regulatory processes.

Recommendation 19: Transparency and stakeholder input are foundational to the development of meaningful consent policies. While the HIA, Inc. Board has responsibility for overall governance of its health information exchange services, consent policy development should be led by the Office of Health Strategy (OHS) and advised by the Health IT Advisory Council. The process proposed is as follows:
a. The Health IT Advisory Council should draft, review, and approve consent policies for the health information exchange that are conformant with these Guiding Principles and State and Federal law;
b. The Health IT Advisory Council may choose to convene ad hoc or standing work groups to support consent policy development;
c. Once consent policies have been endorsed by the Health IT Advisory Council, OHS should review the recommendations and determine any necessary statutory or regulatory actions that may be required;
d. HIA, Inc. will be responsible for the implementation and maintenance of consent policies adopted by the State through OHS policy, statute or regulation;
e. Should HIA, Inc. have concerns about any consent policies received from OHS, it may request a meeting with OHS to resolve those concerns; such resolution may require a review of proposed changes by the Health IT Advisory Council;
f. All meetings of the Health IT Advisory Council are open to the public and the public is provided an opportunity to make comments at each meeting, including comments related to consent policies;

g. All board meetings of the HIA, Inc. are open to the public; and
h. Draft consent policies should be made available for a 30-day public comment period.

In addition, an in-person session for public review and comment regarding draft consent policies may be considered prior to approval by the Health IT Advisory Council. The Health IT Advisory Council should review and consider recommendations or comments from the public to determine whether revisions to policies should be made.

CHA comment: We have comments and two questions about Recommendation 19.

Comments. Pursuant to Section 17b-59e(b) of the Connecticut General Statutes, hospitals and laboratories are mandated to participate in the State HIE, as follows:

> Not later than one year after commencement of the operation of the State-wide Health Information Exchange, each hospital licensed under chapter 368v and clinical laboratory licensed under section 19a-30 shall maintain an electronic health record system capable of connecting to and participating in the State-wide Health Information Exchange and shall apply to begin the process of connecting to, and participating in, the State-wide Health Information Exchange.

The steps that a hospital or lab must meet to be compliant with the mandatory participation clause in Section 17b-59e are still unknown. We also do not know which data will be required to be sent to the State HIE in connection with the statutory mandate to participate. Importantly, a state law mandate to participate in the State HIE is not sufficient under HIPAA to also mandate sharing of protected data.

Hospitals and labs are not allowed to delegate their HIPAA compliance obligations to the State HIE. However, HIPAA recognizes that a state may expressly mandate reporting or disclosure of protected health information under the "required by law" rule discussed in 45 CFR 164.512.

To the extent that the state, or the State HIE, intends to require by law certain data be disclosed by hospitals and labs (and other providers) to or through the State HIE, the detailed requirements of 45 CFR 164.512 would need to be met.

Consistent with the consent principles, and state law governing the operation of the State HIE, required-by-law data collection mandates should be clearly explained in patient education materials, consent policies, and forms. Otherwise, patients will not have a full or fair picture of their rights, or options, regarding consent for sharing their data with the State HIE.

Response to CHA: Your input on this topic is helpful. OHS is committed to ensuring clarity on the topics you raised throughout the regulatory process, to avoid the concerns regarding participation and potential conflicts with Federal rules that you note.

Question 1: Recommendation 19 describes various process steps that OHS and the Health IT Advisory Council will take to ensure development of the consent policies for the State HIE. To what extent are those steps, and the final consent policies that result, subject to due process and administrative procedures applicable to state agencies?

Answer to CHA Question 1: Thank you for this clarifying question. OHS is pursuing the standard process and administrative procedures applicable to state agencies in developing its consent policies. OHS also clarifies that it is the agency authorized by statute to administer health information exchange, including related consent issues, and that the HITAC acts solely as an advisor to OHS.

Question 2: To what extent are actions and decisions of HIA subject to due process and administrative procedures applicable to state agencies?

Answer to CHA Question 2: Thank you for this additional clarifying question. HIA is chartered as a nongovernmental nonprofit entity that is governed by articles of incorporation, by-laws and a conflict of interest policy developed jointly by OPM and OHS that balances independent operating flexibility and efficiency within a firm doing business on behalf of the state. HIA must be compliant with applicable Federal and State statutes and regulations as it pursues its public good mission.

9) Health Equity Solutions.

Health Equity Solutions is grateful for the opportunity to comment on the proposed Guiding Principles contained in the Final Report and Recommendations of the Consent Policy Design Group. We strongly support the state's efforts to create consent policy that informs consumers about how their data will be used and provides accountability through measures to mitigate risks associated with consumer participation. Overall, we support the capabilities of the health information exchange (HIE) and its role in improving the quality of care and patient outcomes through a smooth flow of information between systems. We are committed to ensuring that the consent processes and policies related to the HIE do not contribute to unintended consequences or undue burdens for low-income communities or communities of color in Connecticut.

In order to center health equity in the data consent policy for the statewide Health Information Alliance, respectfully suggest the following:

• Often, consent documents can be lengthy and challenging to digest. Thoughtful education and outreach will be required as referenced in Recommendation 1, 2, and 3. We support having an opt-out policy but implore you to make the explanation of this option clear, concise, and provide a sufficient window for response. We suggest consumer education materials about health information sharing choices, data use, and the consent process be explicitly required to align with health literacy principles and be inclusive of consumers of multiple backgrounds, reading levels, and language proficiencies.

• Data security is a top concern among the consumers we have spoken to across the state, as emphasized in recommendation 12. We suggest a principle that addresses possible compromises in data security. Given our national history of taking the health information of and engaging in untested health practices on marginalized communities without consent, security may be of particular concern to these groups.

• Recommendation 6 acknowledges the additional burden placed on providers to implement consent yet does not recognize the history of coercive practices targeted towards communities of

color in the medical setting. We suggest requiring providers to engage in training that supports integrity in the consent process.

• Recommendation 15 aims to institute a process for addressing consumer complaints. We suggest that this process be both transparent and timely to provide a measure of accountability and to increase the likelihood that any patterns in complaints are detected.

Thank you for taking the time to consider our comments. We look forward to the success of the statewide health information exchange and robust consent policies that center on the needs of consumers.

Response to Health Equity Solutions: Thank you so much for your comment and your engagement on the issue of Consent in Connecticut. Suggestions such as requiring providers to engage in training that supports integrity in the consent process, ensuring data security, and health literacy are topics that will be considered as policy is developed as well as with respect to implementation and monitoring of the policies. We believe it will be very important to have education and outreach on these issues to inform patients. Consistent with Guiding Principles 2, 3, and 6, information shall be made widely available to patients, providers, and other stakeholders about the opportunity for patients to opt-out of data being exchanged across the HIE during this interim time period until the consent management solution is in place. This solution will allow individuals to set their Consent preferences. This will include clear, concise information and a sufficient time period for response. Consumer education materials about health information sharing choices, data use, and the consent process will align with health literacy principles and be inclusive of consumers of multiple backgrounds, reading levels, and language proficiencies.

10) Universal Health Care Foundation of Connecticut.

Universal Health Care Foundation of Connecticut appreciates the opportunity to comment on the proposed Guiding Principles contained in the Final Report and Recommendations of the Consent Policy Design Group of the Health IT Advisory Council.

Universal Health Care Foundation envisions a health system that is accountable and responsive to the people it serves; that supports our health, takes excellent care of all of us when we are sick, at a cost that doesn't threaten our financial security. A well-functioning health information exchange (HIE), could be a crucial tool to bring us closer to this vision. But it must appropriately balance the need for health information data sharing to improve care with the need for privacy protections and truly informed consent.

We are glad to see an overall emphasis on several key themes, including:

• Policy decisions will need to be revisited regularly, given that both consent and data privacy are fields that are evolving rapidly

• Well-designed, understandable consent forms and accompanying educational materials will be necessary to ensure that patients comprehend the consent decisions they are making regarding the HIE

• Consent policy will vary, depending on the nature and sensitivity of the data in question

HIEs rely on trust between patients and providers. Marginalized communities, particularly people of color, have endured a history of privacy breaches and testing without consent, leading to a higher bar to build and maintain that trust. The principles should explicitly acknowledge this challenge. And they should state the need for cultural competence, sensitivity, and humility in the development of both consent policies, educational materials, and provider training.

Finally, recommendation 19 lays out a process for developing consent policy going forward. It rightly emphasizes transparency and stakeholder input, but it also relies heavily on the Health IT Advisory Council. The Foundation would like to see improved representation of consumers on the council.

While industry and patient interests may often be aligned, that is not always the case. It is crucial that patient protections remain top-of-mind as policy is developed. Note that recommendation 6 states, "Consent policies should result in the lowest possible burden on providers responsible for their implementation and maintenance, without compromising the need for sufficient patient understanding and ability to exercise meaningful consent." To maintain this balance, it is important for consumers to be well-represented on the Advisory Council. This representation should also reflect the racial and ethnic background of Connecticut residents.

Response to the Universal Health Care Foundation of Connecticut: As you've noted, the keys themes underlying OHS' work on the HIE's consent model must be clear, current, easily accessible and understandable, and meaningful to all impacted, including patients as well as their providers. Trust underpins all of this work, and pursuant to Conn. Gen. Stat. 17b-59g, requires that the HIE be a "neutral and trusted entity that serves the public good". Accordingly, although the consent regulatory process includes significant transparency and opportunity for public input, OHS and the HIE are developing a complimentary consumer outreach and education process that incorporates best practices for this type of work. Other states have implemented consent policies similar to Connecticut's broad model, and we are actively seeking insights and opportunities from these states to inform this design. While complex, it is crucial that we do this right, so we remain open to, and actively seeking, suggestions to help ensure that all impacted by this consent model have reasonable and equitable access to information and support about the State's consent process, that such information is appropriate and incorporates the CLAS standards, and timely. Key areas of focus may include, but are not limited to: 1) requiring providers to engage in training that supports integrity in the consent process, 2) health literacy, 3) unique patient populations, 4) opportunities to maximize patient understanding of the policy and more. Based upon your input, a recommendation was made to the HITAC to include language in its charter encouraging more diversity in appointments made to the Council. The recommendation was accepted, and the HITAC Charter was affirmed at the April 16, 2020 meeting. Solicitation for consumer representation on the HITAC will be forthcoming.