History of Consent Design
December 2019

Consent Design Group

- The Health IT Advisory Council charged the Consent Design Group with the responsibility for **recommending an initial approach** to patient consent and an **ongoing structure and process** for evolving the consent model as health information exchange in Connecticut matures and expands over time.
- The Consent Design Group's work occurred over **thirteen meetings** from **April through November** of 2019.
    - Please refer to Table 1 for Meeting Dates, Objectives and Materials.
    - The meeting schedule and meeting materials were consistently posted publicly ~1 week in advance of meeting.
    - All individuals were welcome to submit public comment during these meetings. There were no public comments submitted.
- The following individuals were members of the Consent Design Group:
    - Stacy Beck, Anthem Clinical Quality Program Director
    - Pat Checko, Consumer Advocate
    - Carrie Gray, UConn, Director Information Security, HIPAA Security Officer
    - Susan Israel, Patient Privacy Advocate
    - Rod Rioux, CHCACT, Network Director
    - Rachel Rudnik, UConn, AVP, Chief Privacy Officer
    - Nic Scibelli, Wheeler Clinic, CIO
- The **original objective** of the Group was to develop a draft consent policy for review by the Health IT Advisory Council, and ultimately for the Health IT Advisory Council to recommended draft consent policy to OHS to develop proposed regulations, that would address data sharing and data use requirements for the initial use cases planned for early-stage implementation by the statewide health information exchange, Health Information Alliance, Inc. (HIA).
    - This **objective was modified** during the Consent Design Group discussions to focus on **guiding principles** that could inform OHS policy making or HIE operational activities**.**
- At the culmination of the Consent Design Group process, the **majority of Design Group members** came to **consensus on a set of Guiding Principles** which they recommend be used when developing consent policy specific to any current or future HIE use cases. With a subject matter as complex and nuanced as consent, a range of perspectives are to be expected. The Guiding Principles can be found in the Final Report.
- **All members** were invited to **add their individual perspectives and comments** on the Guiding Principles for consideration by those involved in consent policy development in the future. These can be found in Appendix A of the Final Report.

Health IT Advisory Council

- The status of the Consent Design Group was discussed at the Health IT Advisory Council meetings during April to November. The public is welcome to provide comment in this forum as well. Updates and progress were discussed at the following meetings:
    - May 2019 – Consent DG was discussed, no public comment regarding consent
    - August 2019 – Consent DG was discussed, no public comment regarding consent
    - September 2019 – Consent DG was discussed, no public comment regarding consent

- October 2019 – Consent DG was discussed, Susan Israel submitted a public comment related to patient consent and the PDMP.
- November 2019 – The Consent Design Group's Final Report & Recommended Guiding Principles were presented to the Health IT Advisory Council. Consent Design Group members were invited to participate in the presentation of the recommendations.
    - The Council members had a robust discussion on the Guiding Principles. Members suggested modifications to 4 of the 18 Guiding Principles and suggested adding one.
- December 2019 – The updated Guiding Principles will be reviewed at the December Council meeting. The draft version can be found in Table 2. A public comment was submitted by Susan Israel regarding transparency of medical information and consent management. The comment will be addressed at the meeting. The Health IT Advisory Council will determine whether to adopt or recommend further changes to the Guiding Principles. Upon eventual adoption of Principles by the Council at the December 2019 meeting or another meeting, the Principles will be posted for public comment. Public comment will be shared with the Health IT Advisory Council and OHS and posted on the OHS website. After consideration of public comment, the Health IT Advisory Council will vote on the finalized Principles to recommend to OHS for adoption.
- Consent policy will be discussed by the Health IT Advisory Council at public meetings once the principles are adopted by OHS.

Table 1: Meeting Schedule

Meeting Goal and Focus
Meeting #1 (April 9, 1pm-2pm) Kick-off and Orientation
Meeting #2 (April 23, 1pm-2pm) Current Consent Policies
Meeting #3 (May 7, 1pm-2pm) Use Case Approach to Sharing Data
Meeting #4 (May 21, 1pm-2pm) Use Case Approach to Sharing Data (Part 2)
Meeting #5 (June 4, 1pm-2pm) Roadmap to Final Consent Recommendations and Patient Provider Identity Care Map Function
Meeting #6 (June 18, 1pm-2pm) Disclosure Notification Policy Draft Review
Meeting #7 (July 9, 1pm-2pm) Disclosure Notification Policy Draft Review and Update
Meeting #8 (July 23, 1pm-2pm) HIE Governance and Likely Initial Use Cases
Meeting #9 (September 17, 1pm-2:30pm) HIE Governance and Likely Initial Use Cases (Part 2) & Guiding Principles Introduction
Meeting #10 (September 24, 1pm-2:30pm) Review Guiding Principles
Meeting #11 (October 15, 1pm-2:30pm) Review Guiding Principles
Meeting #12 (October 29, 1pm-2:30pm) Finalize Guiding Principles
Meeting #13 (November 12, 10am-11:00am) Review and Finalize Final Report & Recommendations

Table 2: Updated Guiding Principles

Guiding Principles
Recommendation 1 *Consent policies should require patients be provided clear and detailed information about health information sharing choices under applicable State and Federal law.* • Please refer to Additional Considerations for further comments on this Guiding Principle from one or more Design Group members.
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.[1] Educational content should be reviewed and approved by the Health IT Advisory Council, and should not only include information for patients, parents and guardians, but also for providers, pharmacies, labs, health plans, state and local government agencies, and employers. The information should be translated for non-English speakers and should conform to the Web Content Accessibility Guidelines[2] developed by the Web Accessibility Initiative (WAI), part of the World Wide Web Consortium (W3C).[3]*
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).*
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.*
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).*

[1] Adapted, with permission, from the CARIN Alliance Trust Framework and Code of Conduct (https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/)
[2] https://www.w3.org/WAI/standards-guidelines/wcag/
[3] https://www.w3.org/WAI/

- Please refer to Additional Considerations for further comments on this Guiding Principle from one or more Design Group members.

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.

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.

Recommendation 8

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

- Please refer to Additional Considerations for further comments on this Guiding Principle from one or more Design Group members.

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.

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.

Alternative: Delete Recommendation 10

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.

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.

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.

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.

Recommendation 15

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

Recommendation 16

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

Recommendation 17

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

Recommendation 18

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

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 and a public hearing should be considered prior to approval by the Health IT Advisory Council and the Health IT Advisory Council should review and consider recommendations or comments from the public to determine whether revisions to policies should be made.*

- Please refer to Additional Considerations for further comments on this Guiding Principle from one or more Design Group members.