

Consent Policy Design Group

Guiding Principle

Compilation of Responses from Design Group Members & Suggested Recommendations

October 15, 2019

Principles	Accept	Accept with Changes	Don't Accept	Unable to Respond	Proposed Changes
Recommendation 1: COMPLETED					
Recommendation 2: COMPLETED					
Recommendation 3: COMPLETED					
Recommendation 4: COMPLETED					
Recommendation 5: COMPLETED					
Recommendation 6: COMPLETED					
<p>7. Clearly written information about consent policy changes should be provided by HIA, Inc - 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.³</p>	3			1	<p><u>Internal Review:</u> Seems closely related to #3. Maybe consolidate this message?</p>
	SB, NS, PC			RR	
Recommendation: TBD 10/29					

Commented [R1]: Again, why would this be provided by HIA rather than OHS?

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Other considerations:					
7.8. Mechanisms, including digital tools, for expressing consent policy preferences should be user-friendly and easily accessible.	3			1	(PC) Implies everyone has access to and basic literacy to use digital tools. Should there be a paper option
	SB, NS, PC			RR	
Recommendation: TBD 10/29					
Other considerations:					
Recommendation 9: COMPLETED					
Recommendation 10: COMPLETED					
Recommendation 11: COMPLETED					
Recommendation 12: COMPLETED					
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.	3			1	
	SB, NS, PC			RR	
Recommendation: TBD 10/29					
Other considerations:					
Recommendation 14: COMPLETED					
Recommendation 15: COMPLETED					

Commented [R2]: Yes, I agree. This should go without saying. But without clarity as to how this would be accomplished and what it might look like from the Privacy-By-Design perspective, it is hard to say whether what mechanisms would be appropriate. It is also not clear from how this is worded what "digital tools" would mean. Does that mean there is a way for an individual patient to login to the HIE and consent? Is this a datafeed that happens on the Healthcare Organization's side that blocks a patient's information from going to the HIE if affirmative consent is not received? Or if we are going via an opt-out methodology (and again, we have not determined as group whether a recommendation for opt-out vs. a recommendation for opt-in is more appropriate for consent for this HIE or other exchanges using State tools), how that would be addressed digitally or electronically? We do not have enough information as a group to even say whether this very basic thing that we probably could all agree to as a group as a recommendation is even appropriate.

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Commented [R3]: It is hard to comment on this proposed principle without clarity as to what is meant by the term "be aligned with...."

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16. OHS should consider pursuing regulations that define requirements for compliance with consent policies.	3 SB, NS, PC			1 RR	
Recommendation: TBD 10/29					
Other considerations:					
17. Consent policies should require that patients have sufficient time to review educational material before making a consent decision. ¹	3 SB, NS, PC			1 RR	
Recommendation: TBD 10/29					
Other considerations:					
Recommendation 18: COMPLETED					
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: <ul style="list-style-type: none"> a. The Health IT Advisory Council should draft, review and approve consent policies for health information exchange that are 					

Commented [R4]: What does this mean? Why would there be a time crunch for a patient to decide? Again, whether we do an opt-in or an opt-out may matter here. If sharing is not going to be automatic, then a patient should be able to take as long as they like to decide. If the process is going to be automatic based upon a decision to put this simply in NPP's and then let patients opt out either affirmatively, or by choosing not to receive healthcare at an organization that participate in this and/or exchanges, then this time element becomes irrelevant.

¹ Adapted from ONC, HealthIT.gov Meaningful Consent Overview (<https://www.healthit.gov/topic/meaningful-consent-overview>)

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<p>conformant with these Guiding Principles and State and Federal law;</p> <p>b. The Health IT Advisory Council may choose to convene ad hoc or standing work groups to support consent policy development;</p> <p>c. Once consent policies have been endorsed by the Health IT Advisory Council, OHS will review the recommendations and determine any necessary statutory or regulatory actions that may be required;</p> <p>d. HIA, Inc. will be responsible for the implementation and maintenance of consent policies adopted by the State through OHS policy, statute or regulation;</p> <p>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;</p> <p>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;</p> <p>g. All board meetings of the HIA, Inc. are open to the public; and</p> <p>h. Draft consent policies should be made available for a 30-day public comment period</p>					

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prior to approval by the Health IT Advisory Council.					
Recommendation: TBD 10/29					
Other considerations:					