

Consent Policy Design Group

Meeting Minutes

MEETING DATE	MEETING TIME	Location
October 15, 2019	1:00PM – 2:30PM	Join Zoom Meeting: https://zoom.us/j/269726549 Dial: +1 646 876 9923 US Meeting ID: 269 726 549

DESIGN GROUP MEMBERS

Stacy Beck, RN, BSN	X	Susan Israel, MD	X	Nic Scibelli, MSW	X
Pat Checko, DrPH	X	Rob Rioux, MA		Rachel Rudnick, JD	X
Carrie Grey, MSIA					

SUPPORTING LEADERSHIP

Allan Hackney, OHS		Carol Robinson, CedarBridge	X	Sheetal Shah, CedarBridge	X
Tina Kumar, OHS		Michael Matthews, CedarBridge	X	Tim Pletcher, Velatura	
Sean Fogarty, OHS	X	Chris Robinson, CedarBridge		Lisa Moon, Velatura	

Minutes

	Topic	Responsible Party	Time
1.	Welcome and Overview	Michael Matthews	1:00 PM
	Michael Matthews welcomed the group and provided an overview of the agenda.		
2.	Public Comment	Attendees	1:02 PM
	There was no public comment.		
3.	Review and Approval of Meeting Minutes	Attendees	1:05 PM
	Pat Checko asked to correct the 3 rd paragraph; she said that the concept of opt-in or opt-out is not clearly understood by the public. Michael indicated that this will get updated. Pat Checko created the motion to approve the meeting minutes from September 24, 2019. Susan Israel seconded the motion and it was approved without objections or abstentions.		
4.	Discussion of Guiding Principles	Attendees	1:10 PM
	<p>Michael indicated that the group reviewed 9 principles during the last meeting, 2 were referred to Rachel Rudnik and there were 9 left to review. He said that he and Sheetal had a conversation with Rachel this morning to review the design group’s deliberation last week, so there are additional comments and verbiage to be addressed. He proposed to go through the language on which they reached some degree of consensus and then devote the rest of the time to the remaining 9 principles. No one disagreed with this approach.</p> <p>Principle #1:</p> <p>Michael reviewed the first principle. He asked Rachel for affirmation. Rachel said she was comfortable with the changes made. She also indicated that she appreciated Susan’s comments in reference to this principle.</p> <p>Michael said that space was created for members to offer additional perspectives or considerations for others crafting policy. He proposed that this group will have one more meeting and a “homework” exercise to share any other perspectives associated with each principle. There will also be a space for general comments which may not be specific to a principle.</p> <p>He inserted Susan’s comments under the first principle with her approval. He said that this is how it would be displayed in the final report; any and all of the members’ comments would be included. He asked if Susan would like to speak to the comments she made under this principle.</p>		

Susan said that she had written it as one statement but then inserted numbers, if the group did not want it to be added to the principle above. For example, she would like to see “1) patients must be allowed to opt-out of the HIE” in the guiding principle. If the group did not want to include this, then she would like to see if information under section 2, subsequently 3, 4, and 5 could be added to the principle.

Michael asked if the members would like to add these sections to the principles or if they would prefer to have this under the other considerations section. Pat explained that she would have issue with a simple “allowed to opt-out” statement and prefer to leave it as is. Rachel indicated that without full information on the technical aspects or functionality, she would be concerned with having it in the guiding principle. She definitely thinks it should be a consideration.

Michael asked for other comments. No one else provided comments. He suggested to leave the principle and other considerations as is. He thanked Susan for her flexibility and how she provided context to the group.

Principle #2:

Michael reviewed the edits to this principle. Rachel strongly advocated for the modification made to remove “dependent on funding availability,” as this should be a requirement. Rachel affirmed her acceptance of the principle.

Principle #3:

Michael provided an overview of this principle and clarified the role of HIA. He indicated that this principle is specific to the distribution of educational resources. Rachel and Susan accepted this principle with changes.

Principle #4:

Michael provided an overview of this principle. He said that the essence is not about who is doing the review, but that the review should be done before a use case is put into production.

Susan said that she would like to include two updates: 1) accepted by the Health IT Advisory Council and 2) to combine #16 and #4. She indicated that she would like to see the consent policies go through the regulatory process. Pat asked for clarification on what specifically would go through the regulatory process, as this could take years. Susan indicated that she wants to ensure that the process is transparent and suggested the Health IT Advisory Council. Rachel asked if they were the right party, as it may be broader or need subject matter expertise. In addition, Rachel believed that #4 and #16 should remain separate.

Michael offered a suggestion to insert language “by appropriate subject matter experts” into the principle. The group deliberated on this aspect, discussing the role of the experts and the process by which this would occur. Michael stated that the purpose of this principle was to not launch a use case into production until there was a consent policy review. The other issue he heard is about who is developing and then reviewing policy. He was concerned that they may be conflating these two concepts into one. The group agreed that it was fine to insert “subject matter experts” as this did not define the locus of those experts. Michael proposed to draft another principle (#19) which will take up the issue of “who” and “how” of policy development. He asked the group for their feedback on this approach. Rachel indicated she was comfortable based on this discussion. Susan, Pat and Stacy agreed that they would be comfortable with this principle if another principle addressed how the policy gets developed and who reviews it.

Principle #9:

Michael asked Rachel to provide background on the suggested language. Rachel said that she was concerned with the language that was used, specifically the word “authorization” as this is the mechanism by which consent is received. She believed she understands the intent of this principle and suggested changes to the wording. Michael asked the group for their thoughts.

Pat Checko was okay with substituted language, as Rachel had more experience in this area. From her perspective, the wording implies what will happen to patient data.

Damien Fontanella introduced himself to the group; he is General Counsel with OHS. He asked about the intent of this principle. Rachel explained that an organization should be able to explain what happens if a patient withdraws their consent. It should have a full explanation if a patient does not want their data shared via the HIE. Damien agreed; he indicated he was not sure how to balance the level of information needed to explain what happens to the data. He also wanted to ensure that they not using language that would make people afraid to participate.

Michael said that he liked the simplicity of the statement. Rachel said if they are aiming for transparency, consent policies should “comprehensively explain” what will happen if consent is revoked. The group deliberated on specific wording.

Carol Robinson indicated that there are systems to manage revocation, as there is also a difference between one time consent or blanket consent. She suggested that the language could be broader, but potentially be clear about the technical capabilities and policies for time-limited consent and consent revocation. She asked if this resonated. Rachel said it did. Rachel indicated that there are technical aspects of what can be done, from both the provider or research perspective, and they need to understand what happens for patients and their data if consent is revoked.

Michael offered and reviewed updated language with the group. Stacy, Pat, Rachel and Susan agreed with the updated language.

Principle #10:

Michael indicated this principle was referred to Rachel’s judgement. Rachel added a preamble with an additional modification. Stacy, Pat, Rachel and Susan agreed with updated language.

Principle #11:

Michael indicated this principle was referred to Rachel’s judgement. Rachel added a preamble with an additional modification. Stacy, Pat, Rachel and Susan agreed with updated language.

Principle #12:

Michael reviewed this principle with the group. Rachel is supportive of language. Pat is supportive too but would like to point out that STDs and HIV are no longer specifically protected. Susan said that she read that there may be changes to substance use data under 42 CFR Part 2 and hopes that Connecticut can consider the concern of substance use data. Michael asked if they should be silent on the examples and say that it should be in alignment with sensitive and specially protected data. Susan said she would not like this as federal and state statutes may change.

Rachel asked if there were any other consent practices or guidance that come from professional organizations or advocacy groups. For example, they could insert language like “in accordance with industry best practices,” but is not sure if this is relevant.

Carol Robinson suggested that the group needs to be careful in remembering the delineation between guiding principles and setting recommendations for policy. She believes that organizations have to adhere to federal and state law. Therefore, if the guiding principle is to consider other data to be sensitive under a policy that was not governed by law, this could be problematic and received with some confusion. Susan said she understands Carol’s point. She asked if there was anything they could put in the other considerations section related to the potential change to 42 CFR Part 2. Carol said that it may be challenging because the rule is still in proposed language. She suggested that the group could recommend developing further legislation.

Damien said that these are just guiding principles for consent policies, it is not a formal requirement being imposed on any particular provider. He indicated that the principle is that everyone will follow applicable law and could include the clause “as may change from time to time,” as the laws may evolve. He is also supportive of including the examples of data so the reader has a better understanding of what this principle means. He indicated that all the other questions are legitimate but that they may not be addressed in this document. There are pending changes at the federal level, but those changes may or may not happen 3-6 months from now.

Michael asked if the group was supportive of the updated proposed language. Pat, Rachel, Stacy and Susan agreed.

Principle #14:

Michael reviewed the changes made to the principle. Rachel was in agreement with the modified language. Susan also accepted with changes.

Principle #15:

Michael asked the group if they accepted the principle as written. No one disagreed.

Principle #18:

Michael asked the group if they accepted the principle as written. No one disagreed.

Principle #5:

Michael provided an overview of Rachel’s consideration related to the Notice of Privacy Practices (NPP). He suggested to shorten the statement and asked for Rachel’s guidance. Rachel said that since this is supposed to be a guiding principle, adding “exchange or exchanges” is an important step. However, she is not sure if they should go a step further to include that health care organizations should provide a location or link so patients can find more information on which electronic exchanges providers participate in. She indicated that this is her personal opinion, she is not sure if her organization would agree to this.

Michael asked the group if there is support for the language proposed. Damien indicated that he liked the wording of this principle. He also liked the idea of requiring more specific information, but it may not be feasible to require it. Pat asked if they could include Rachel’s comment in other considerations which was inserted for note taking purposes. Pat was supportive of this language, no one dissented.

Principle #6:

As it related to the term “provider burden,” Michael said this concept that has been promoted by the National Coordinator for Health IT. He asked the group for their feedback. Pat said that she still wants to ensure that the patient receives ample information. Rachel indicated that she did not have enough information to make an informed decision, as she is not sure what type of burden they are trying to minimize. Michael offered a hypothetical example: every patient needs to have a 1:1 informational session with qualified staff in the practice about the sharing of their health information. He indicated that this is an example that would create provider burden. He suggested adding language based on Pat’s concern. Susan added that she did not want burden to translate into cost.

The group added the term “informed” consent. Carol indicated that the “informed” consent has a specific meaning in clinical trials, since IRB requires this phrase. Pat suggested the to use the term “meaningful.”

Michael reviewed the updated proposed language. Pat Checko agreed, no one dissented.

5.	Wrap Up and Meeting Adjournment	Michael Matthews	2:25 PM
	Michael said he thinks it will take two more meetings to get through the remainder of these principles and the final report. At the next meeting, they will go through the remaining principles (7, 8, 13, 17) and proposed		

language for #19. The first “homework” assignment from this meeting will be for the group to review and add other considerations to the principles that were accepted today. Finally, he would like the group to also give thought to general comments for those developing the consent policy.

Michael suggested that the next meeting will be held October 29, 2019 from 1-2:30pm. Rachel said she has a hard stop at 2pm. Stacy is flexible. Pat said she can adjust.

DRAFT