Readout
Substance Workgroup Meetings
May 18 and 20, 2020

Thank you to everyone who joined and participated in our May meetings. Both meetings were conducted via teleconference due to the Coronavirus - COVID-19 and enjoyed productive and lively discussions. Over 40 people participated in the May meetings. A list of participants is included at the end of this document.

As a reminder, the goal of this workgroup is to develop the content of a framework for unregulated health information. The May meetings focused on possible exceptions to the general protections that would apply to covered data. Now that we have completed all of the planned meetings of this workgroup, we are currently working to incorporate the feedback from these meetings into a draft framework. Once that draft is complete, we plan to circulate it in advance of July's meeting of the steering committee.

Possible Exceptions Under the Framework:
During the May meetings, the workgroup discussed possible use exceptions around research, de-identified and aggregated data, public information, and allowances for the internal operations of the website or online service. This summary will focus on the areas that garnered the most discussion during the May meetings. However, as workgroup members continue to think about and work on these issues, we encourage you to provide additional feedback on all sections of the May agenda, or previous meetings.

Research:
Should the framework permit the use of consumer health information for certain types of research without needing consent from users? There was uniform agreement from meeting participants that a research exception is appropriate. Both meetings discussed how to define the universe of permissible research and what models to look to. Several members highlighted that if the framework links research to a "public interest," the framework will need to define that term. Additionally, there was discussion around certain types of research focused on consumer marketing and market research and whether that should fall within the general research exception.

Both May sessions also discussed if the framework should include the use of internal review boards and privacy boards as a way to preserve consumer privacy while also allowing certain sets of data to be used for research without consumer consent. There was general consensus and comfort with including a review board, especially since similar boards already exist under HIPAA. We also discussed how frequently and under

what circumstances such review boards would be utilized. A couple outstanding questions include:

- ➢ *Outside of de-identified data sets (discussed later), are there ever certain uses and/or data sets where certain kinds of research are acceptable without the need for an independent review?*
- ➢ *Should internal product improvement and business analysis ever fall under a research exception?*

De-identified and Aggregated Data:
Should the framework permit the use of de-identified or aggregated consumer health information for certain types of research without needing consent from users? Again, the general consensus from the group was yes. The main discussion points focused around the difference between "de-identified data sets" compared to "aggregated data sets."

There was general comfort with the concept of truly aggregated data being used without consumer consent. When discussing de-identified data, the group worked through how best to take identifiable data and de-identify it. We also discussed if data could ever truly be de-identified, especially for certain individuals or groups. There also seemed to be a preference for favoring statistical approaches and verification for de-identifying consumer health information over listing out and then removing certain identifiable pieces of information from each individual's record.

- ➢ *Should the framework always condition the use of de-identified data only if it meets certain statistical thresholds in order to protect individual privacy?*
- ➢ *Should the standard for using de-identified data mirror the statistical requirements under HIPAA?*

Finally, we discussed if the framework should contain a requirement that entities provided with de-identified data not engage in any activity that attempts to re-identify data. There was robust discussion about how these obligations would apply to third parties and also circumstances where limits on disclosing de-identified data may limit what public health officials can do, especially in emergencies.

- ➢ *Should the framework contain a requirement that entities seeking to use de-identified or aggregated data contractually commit to make no attempt to re-identity the data they receive from the consumer or another entity?*
    - ➢ *Should that commitment be public?*

Emergency Use and Other Exceptions:
The group agreed that the framework should include an emergency exception that allows an entity to disclose consumer health information to a medical professional/health care provider, if that entity, in good faith, believes that an emergency involving danger of death or serious physical injury to any person requires disclosure relating to the emergency. The group was also generally receptive to the inclusion of other exceptions that allow entities to ensure that their services function properly and protect consumer health information. Members of the workgroup also encouraged the inclusion of data security provisions.

Finally, we discussed exceptions for information that is publicly available. Critical to this portion of the discussion was encouragement around drafting this exception to capture truly public information while not being over- or under-inclusive.

Thank you all for your continued engagement and involvement with us on this project. We look forward to receiving your feedback.

May Substance Workgroup Meeting Participants:
Aaron Hernandez, Amazon
Alaap Shah, Epstein Becker and Green Law
Alice Leiter, eHI
Amy McDonough, Fitbit
Andrew Crawford, CDT
Anil Swani, UC Berkeley
Ann Funai, Under Armour
Ann Waldo, Waldo Law
Ben Moscovitch, Pew Charitable Trust
Bray Patrick-Lake, Evidation Health
Carlos Gutierrez, LGBT Tech Partnerships
Catherine Pugh, eHI
Corey Cutter, American Cancer Society
David Brody, Lawyers' Committee
Dena Mendelsohn, Elektra Labs
Deven McGraw, Ciitizen
Erica Finkle, Facebook
Henry Claypool, American Association of People with Disabilities
Jennifer Bordenick, eHI
Joanna Calabria
Joanne Charles, Microsoft
Jules Polonetsky, Future of Privacy Forum

Katherine Hempstead, RWJF
Laura Hoffman, American Medical Association
Lee-Berkeley Shaw, CDT
Leslie Kelly Hall, Healthwise
Lisa Hayes, CDT
Mark Segal, DIG-HPA
Melissa Bianchi, Hogan Lowells
Michelle Huntley, United Health Group
Nicol Turner Lee, Brookings
Rachele Henricks-Sturrup, Future of Privacy Forum
Rebecca Cady, Children's National Health System
Ridhi Shetty, CDT
Rob Tennant, MGMA
Sean Kennedy, Salesforce
Shawneequa Callier, GW School of Medicine
Susan Bouregy, Yale
Toke Vandervoort, Under Armour
Varoon Mathur, AI Now
Yael Weinman, Verizon