

Privacy Subcommittee hearing of the National Committee on Vital and Health Statistics
Governance Considerations Panel – April 17, 2012
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I focus these remarks on two areas: (1) responsibility to engage the public throughout the lifecycle of a research initiative and also (2) on the Catch-22 of anonymization. I recognize the committee will be hearing issues in this spectrum throughout the day, so I tie my comments to the framework of governance for the purposes of this opening panel. Further, each of these areas hinges critically on how we interpret the responsibility to **demonstrate respect for participants** and **assure that research benefits outweigh the risks**, particularly when considered **from the perspective of the participants themselves**. These are old-fashioned research ethics concepts from the 1979 Belmont Report, and yet, our current regulatory models of anonymizing datasets alone may not be accomplishing these critical foundations of research ethics (Fullerton et al. 2010).

Governance generally refers to the organizing structure of leadership and decisionmaking within the research collection or research initiative¹. There are a series of decisions that each research collection will face: which population, which data, for what purposes, for use by whom, what accountability processes will be used, what communication mechanisms and requirements will be utilized for data sources, data users, and for the public. These governance decisions are often made by a steering committee. My colleagues and I have argued for a **participatory governance model**, that goes beyond the usual Community Advisory Board (CAB) limited consultation to a more integrated approach throughout the oversight infrastructure (see O’Doherty et al. 2011). That said, we recognize the level of investment in governance will need to be **weighed against important contextual features**, such as: what is the existing level of trust and cohesion within the community? How effectively could a CAB be trusted and utilized? What other communication mechanisms will be employed? What is the nature of the dataset and the work proposed? What is at stake if people are surprised by the choices made? (See Ludman et al. 2011 for an excellent example of weighting some of these trade-offs.)

It will not be necessary to remind this panel of the cautionary tales that have come out of recent research uses of public health collections (Harmon 2010). One response to these cases can be for the public health community to view them as the result of a few individuals who reject the aims of science. On the other hand, we can view them as what can happen when there is a **disconnect between public expectation and actual practice**. From public opinion data (about which you will hear more later today), we know there is a broad majority that are happy to have their data to be used for public health research purposes and do not need to hear much more about it. However, those on the tail ends – from those who support the initiative but will desire much more information and those who will not trust others to make such decisions on their behalf – need to be taken seriously or the entire enterprise can be at risk.

From newspaper stories about the Texas Public Health Department decisions regarding utilizing newborn screening bloodspots for research purposes – appropriately de-identified for secondary use – officials decided not to make public disclosures of the uses because it would be “too complicated” or it would raise concern where really none was warranted (email exchanges

¹ In the case of Community Health Initiatives, I recognize that these are likely to be public databases or collections, such as blood banks, disease registries, or newborn screening bloodspot collections, that will then be considered for research purposes. When shifting in mission from public health management to public health research, new responsibilities and oversight structures will apply. For simplicity, I refer to these entities as “research collections” even though I recognize they stem from diverse sources.

available through FOIA filed by a reporter). In retrospect, this was clearly a mistake. I submit communication about research uses of public health collections is an important **opportunity to raise science and health literacy** to help the public understand how epidemiology and population health research works. Key concepts would be useful to characterize for the public such as the power of large datasets and the goals of looking for patterns and prevalence rather than individual risks or conditions. Understanding the nature of the science itself helps to understand why individual identifiers really are not the point of the projects. Further, if we can **close the feedback loop** at the end of some of our data uses, it can help people understand how the public databases and data sources are being used, how the findings are contributing to public health, and why this research is worthwhile. Simply put, the more we do, the more we share, the more valuable it can appear to everyone involved (Beskow et al. 2012; Saha&Hurlbut 2012).

Thanks to some high-visibility media stories and the best-selling book *Immortal Life of Henrietta Lacks*, people are now more primed than ever to want to know **what happens to their data** or specimens when they leave their bodies, who makes those decisions, who is getting rich, and how those decisions are made. Innovative models for bringing more participants into the on-going oversight and governance of a research repository will help make this black box less dim (see for example: Winickoff 2003; O'Doherty et al. 2011; Kaye et al. 2012). We are also working to humanize data points to help researchers and analysts using those datasets remember that they are attached to people (see the *People Matter* project), and hence, deserve to be handled respectfully and intentionally.

The final point here circles back to the Catch-22 of anonymization as a mode of protecting people. While this may protect their identity, in the absence of further communication or choice it does little to demonstrate respect for persons (Trinidad et al. 2011). The **positive right to privacy** claims that we have **a right to control who has access** to our data. This is the oft-quoted "Facebook generation," who contrary to popular understanding, are making very conscious choices about what information they are sharing and with whom. These are different than the "information altruists" who literally do put all information "out there" for anyone to use for any purpose (Conley et al. 2010). The **participant-centric initiatives** and **dynamic consent models** utilizing social media and online services will make more responsive recontact, notification, or personalized preference setting available in research studies (Kaye et al. 2012; Shelton 2011). The goal of anonymization may be protection, but we have learned from Texas, Minnesota, and other lawsuits such as the Havasupai that this may not be enough to assure people we are working with their best interests in mind. Maintaining connections to identifiers and permitting re-contact with people or data sources may lead to richer scientific projects as well as a stronger ability to let people know how their data is being used, or to withdraw if they express that wish.² Hence, we could do more ethically and scientifically by maintaining connections to participant identifiers. These connections must be stewarded carefully, as suggested above, through governance mechanisms like honest brokers and data access review, data user agreements, and follow up.

In closing, **trustworthy practices require attention to relationships and accountability** (Yarborough et al. 2009). Relationships in the case of community and population health projects require proactive public relations development regarding the purpose and use of the research collections. Accountability means attending to the oversight and feedback loops (potentially with sporadic auditing) to build in assurance and understanding of appropriate use. Assuring trust can be handed off to secondary data users is essential to maintaining the chain of trust

² Note that if data has been truly anonymized, it is not possible to withdraw a person's data from that dataset.

throughout the system (Anderson&Edwards 2010). Demonstration projects from longstanding cohort studies are underway that utilize many of these best practices (see for example: Marshfield, Mayo, Framingham, Strongheart, and the Women's Health Initiative; Yuille et al. 2010 on the values underlying access decisions for the UK Biobank).

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