Public Perception and Policy Development in Consent Standards for Human Research – How Competing Views on Public Goods and Private Interests Shape Data Sharing, Big Data Research, and Other Activities Using Human Data and Materials

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In 2010, a narrative describing secondary use of leftover tumor tissue burst into public consciousness through the New York Times best-seller, The Immortal Life of Henrietta Lacks. The book gave a human face to the woman whose residual ovarian tumor tissue, excised in 1953, later grew into the ubiquitous HeLa cell line used the world over for numerous scientific advances. Movie producers optioned the story, media outlets around the country carried it, and, for many, it exemplified deeply-held beliefs about prejudice, disenfranchisement, social injustice, and exploitation by scientific, medical and other "establishments" at the expense of individual freedom and autonomy. Due in part to these concerns and the popular backlash they engendered, as well as other issues, the U.S. Department of Health and Human Services (DHHS) suggested in 2015 a new approach for research involving existing tissue and data (secondary research) that would have severely limited the conduct of such research without consent. For many, this policy effort represented a gross and short-sighted over-reaction. Concerned about the potential to slow the pace of discovery without attendant ethical benefits, members of the scientific community and other public commenters, including members of the independent DHHS advisory committee charged with advising DHHS on human subjects protection, strongly opposed this effort. In 2017, following extensive public discussion, the DHHS scuttled the proposal, leaving in its place a softer variation authorizing, but not requiring, a new "broad consent" for some secondary research activities. This panel will explore the evolution of the current regulatory system in light of this history as well as other contemporary examples of how individual's expectations to "have a say" in the use of "their" tissues and data play into the shape of both regulatory requirements and extra-regulatory best practices. It will look at other examples like the use of newborn blood spots for research purposes, patient and research subject rights of access to laboratory test results, and the right to place restrictions on the use of data in recent privacy legislation, including Europe's General Data Protection Regulation and California's Consumer Privacy Act. As researchers continue moving forward with data sharing, big data activities, real world evidence development, and other activities to leverage materials and data that derive from humans through the use of new technologies, it is important to understand the ways that public perceptions and advocacy can shape policy development and possibly limit scientific freedom to the detriment of public health.