

VIEWPOINT

Recognition of Research Participants' Need for Autonomy Remembering the Legacy of Henrietta Lacks

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August 1, 2020, marked what would have been the 100th birthday of Henrietta Lacks, the Black woman whose cervical cancer cells gave rise to the immortal HeLa cell line. HeLa cells have played an extraordinary role in scientific research, underlying multiple Nobel Prize-winning discoveries and enabling medical advances for polio, cancer, Ebola virus disease, sickle cell disease, and countless other conditions.

However, the bright biomedical legacy of HeLa cells is tarnished by the injustice of this biospecimen being preserved without the consent of Lacks or her family, whose identity was revealed decades ago.¹ This failure, while permitted by the ethical norms of the time, has affected the Lacks family in profound ways, including limiting the comfort, pride, and satisfaction that comes with knowing a deceased loved one made an important contribution to science. Today's current events provide an opportune time to reflect on the experiences of Lacks and other African Americans in the context of biomedical research, and to look ahead to what can be done to make that future far more just and equitable.

In the wake of the killing of George Floyd and other similar events, the US may have reached an inflection

point (see the accompanying editorial on the drome coronavirus 2). In the US, this pandemic has disproportionately affected Black persons and many other people of color, with Black people experiencing a mortality rate 2 to 3 times as high as White or Asian American individuals.⁵⁻⁷

Scientific and community leaders have begun to emphasize the need to recruit a diverse pool of participants for COVID-19 vaccine trials, even as antivaccination interests attempt to build on the history of mistrust in the Black community to discourage research participation and increase vaccine hesitancy.⁸ In an ironic twist of fate, early work that characterized human angiotensin-converting enzyme 2 (ACE2) as a receptor for SARS-CoV-2 and described the mechanism for entry (which formed the basis for targets for leading vaccine candidates) used HeLa cells,⁹ thus creating a surreal circumstance in which the research and medical communities are asking Black people to have trust in vaccines developed using cells obtained from a Black woman without consent.

What may not be realized about the cautionary tale of HeLa cells, however, is that something quite similar could still happen today. The current system for protect-

ing human research participants does not require consent for deidentified biospecimens obtained from clinical practice—just like Lacks' tumor—to be used in medical research. As the US reflects on the progress that biomedical research has made and, hopefully, how the concepts of equality, ethics, and fairness have evolved in the 100 years since Lacks' birth, perhaps the moment has finally ar-

rived to think about how to rectify the situation regarding biospecimen consent. The time is overdue for the scientific community in the US to demonstrate its respect for all humankind by seeking consent from individuals who contribute literal pieces of themselves to medical research.

This is not a new idea. When revisions to the Common Rule for human participant protections were proposed in 2011, a provision was included that would have required consent for the use of biospecimens in research. While that proposal was retained through the next draft of the revised Common Rule, it was ultimately eliminated when the Rule was finalized in early 2017.¹⁰ Indeed, removing the provision was probably the right thing for the US Department of Health and Human Services' Office of Human Research Protections to do at that juncture. Comments on the proposal made it clear that this major policy shift was not ready for implementation; many details needed to be worked out to ac-

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point in challenging systemic racism and a long history of injustices against Black individuals. The research enterprise must admit to its own ugly scars of institutional racism, from the unethical Tuskegee syphilis experiments on Black men to recent troubling revelations that Black researchers are significantly less likely to receive funding from the National Institutes of Health (NIH) than their White counterparts, and that research involving health care disparities is less likely to be funded.^{2,3} Set against a landscape of well-documented inequities in health care delivery and access, it is no wonder that mistrust of the biomedical research establishment persists in Black communities and has resulted in lower participation rates of Black individuals in many clinical trials.⁴

The underrepresentation of Black participants in research trials has taken on a new urgency as the world faces the greatest public health challenge of this generation in the form of the coronavirus disease 2019 (COVID-19) pandemic, which is caused by the novel coronavirus SARS-CoV-2 (severe acute respiratory syn-

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commodate such a fundamental change in how clinical biospecimens are integrated into biomedical research.

However, NIH maintains that the principle remains sound and is now calling on the scientific community to determine how to move forward to build a firmer foundation of trust. A genuine culture of respect for research participants demands that they be asked to agree to use of their biospecimens, regardless of identifiability. With increasingly sophisticated genomic sequencing technology, interoperable databases, and artificial intelligence/machine learning approaches, the concept of being able to “deidentify” biospecimens for future research use—the critical regulatory delineation between needing consent or not—is rapidly becoming obsolete.

NIH has tried to reflect some of that new reality through a variety of new policies and agreements. Examples include its Genomic Data Sharing policy that requires participant consent for access to human genomic data, and its 2013 agreement with the Lacks family for a special level of review to gain access to the HeLa whole

genome sequence. Still, this piecemeal approach is far from ideal. Solving the issues of inequities in clinical research and, ultimately, in health care and medicine is going to require the recognition and remediation of systemic racism throughout the enterprise. It will not be a simple undertaking: it will require a commitment to substantive change, disruption of the status quo, and a willingness to admit complicity in an unjust system.

As people from many walks of life pause this August to remember the bittersweet legacy of a Black woman who had no say in the use of her precious cells, the US biomedical research community should do more than simply acknowledge that what happened to Lacks and her family was regrettable. It is time to take concrete action by establishing a Henrietta Lacks biospecimen consent policy, and thereby ensure that what happened to this woman and her family will never happen again. As Martin Luther King Jr said, “The time is always right to do what’s right.”

ARTICLE INFORMATION

Published Online: August 11, 2020.
doi:10.1001/jama.2020.15936

Conflict of Interest Disclosures: None reported.

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