Revised Common Rule Strips Parents of Consent Rights Regarding Baby DNA Used for Research

Citizens’ Council for Health Freedom: DNA of Millions of Children Is Collected, Stored, Used, Analyzed and Shared Without Parental Consent

ST. PAUL, Minn.—As things stand, in just over two months parents will lose their consent rights for the use of their newborn baby’s DNA for federally funded research, once the revised Common Rule goes into effect on July 19, 2018.

Citizens’ Council for Health Freedom (CCHF) has been working to ensure that Baby DNA is protected in the final version of the “Federal Policy for the Protection of Human Subjects,” known as the Common Rule. The Trump administration wisely put a hold on the Common Rule, which was supposed to take effect in January 2018. Recently, several government agencies proposed a further six-month delay that would push implementation of part or all of the rule to Jan. 21, 2019.

But regardless of any impending delay, parents should be concerned that the infant dried blood spots used for newborn screenings could be stored indefinitely or used for research, depending on the state of residency, says Twila Brase, co-founder and president of CCHF.

“We know from our own research, research by others and through personal interactions that parents want to have control over whether their baby’s DNA is stored or used for research—or kept private and protected,” Brase said. “The DNA of newborn citizens should not be used for research without parental consent, or later without their own consent as adults who were minors when their DNA was stored by state government without their consent.

“Government officials and agencies cannot take the DNA of adult citizens without their consent except under very defined circumstances,” she continued. “Yet the DNA of many of the 4 million children born each year is collected and stored, available to be used, analyzed and shared without parental consent. Newborn DNA warehousing and research is a secret government ‘taking.’ Most parents do not realize what is taking place in the midst of their exhaustion, joy and vulnerability at the hospital—and they are not asked. But when they figure it out, some of them sue, which is exactly what attorney Philip Ellison did in Michigan—the fifth lawsuit so far.”

In 2014, CCHF secured language in the Newborn Screening Saves Lives Reauthorization Act of 2014 (NBSSLRA) that required parental consent for the use of newborn DNA for federally funded research. The
bill, which was signed into law by President Barack Obama, also recognized research using newborn dried blood spots (DNA) as human-subjects research and prohibited any waiving of these parental consent requirements. *CCHF* worked with the Senate Steering Committee and the office of Sen. Rand Paul on the protective language, which was slated to expire when the Common Rule was finalized. *CCHF* and Paul’s office were led to believe the revised rule would include the parental consent requirements.

However, Brase said, when the final Common Rule was released Jan. 19, 2017, the day before the inauguration of President Donald Trump, the rule specified that the 2014 statutory parental consent language expires, and the language is not retained in the rule. Once the rule is finalized, as early as this summer, those parental consent rights will be gone.

“These newborn genetic screening tests check for certain disorders, which is important for families, but some state health departments are creating large repositories of leftover identifiable newborn data, blood and DNA for medical and genetic research without further consent from the parents,” Brase added. “That is not only alarming for moms and dads, it’s wrong.”

Once the revisions to the Common Rule go into effect, Brase added, the parental consent requirements and human subjects designation of the NBSSLR will be vacated. Currently, if no further regulatory changes take place, the revisions to the Common Rule would go into effect on July 19, 2018, although a delay in implementation is still possible.

Brase added that parents should be concerned that their baby’s genetic blueprint is being used and stored by the government.

“That which the government holds, the government owns,” she said. “A child’s DNA held by the government could be sequenced, meaning a baby’s genetic code could be completely detailed and mapped—and then recorded in a state government database, used and shared. This is private information on America’s tiniest citizens, who will grow into adults stripped of their genetic privacy when they weren’t able to protect themselves.”

*CCHF* first began educating Americans about the use and storage of “Baby DNA” without parental consent more than a decade ago. In fact, *CCHF* successfully helped 21 Minnesota families win a lawsuit requiring all newborn DNA specimens be destroyed by the state health department. Unfortunately, the legislature changed the law and storage began again without parental consent on Aug. 1, 2014. Additional lawsuits by parents, including a new case in Michigan, have also been filed. Read more about *CCHF*’s Baby DNA work at www.ItsMyDNA.org.

For more information about *CCHF*, visit www.cchfreedom.org, its Facebook page or its Twitter feed @CCHFreedom. Also view the media page for *CCHF* here. For more about *CCHF*’s initiative The Wedge of Health Freedom, visit www.JointheWedge.com, The Wedge Facebook page or follow The Wedge on Twitter @wedgeoffreedom.

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