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Agency: Department of Health and Human Services (HHS)

Document Type: Rulemaking

Title: Federal Policy for the Protection of Human Subjects

Document ID: HHS-OPHS-2015-0008-0001

Comment:

ADDENDUM TO CCHF's PUBLIC COMMENTS - "HUMAN SUBJECT" DESIGNATION

Citizens' Council for Health Freedom would like to underscore the importance of the proposed "human subject" designation of biospecimens, including newborn DNA. We support this designation, which is currently in law for newborn dried blood spots (Newborn DNA) under the Newborn Screening Saves Lives Reauthorization Act of 2014.

But as we noted in our previously submitted comment about the parent consent requirement now in statute as a result of the NBSSLRA of 2014, this statutory designation will also expire/disappear as soon as the Common Rule is finalized...unless the Common Rule upholds this critical designation.

The NBSSLR Act of 2014 is the first time the "human subject" designation has ever been granted to biospecimens, and there is very good reason for this statutory protection. After newborn screening is complete, the dried blood spots, stored by state health departments for short-term or indefinitely, are used often without consent for genetic and other research. They are considered a rich source of DNA. Some have called these stored spots, taken from every child at birth, a "national treasure." In some states, the government repositories contain the genetic code of nearly every citizen born in that state over decades.

As the agency notes in the proposed regulation, it's impossible to guarantee in this era of genetic testing and genomic sequencing that a person will not be identified simply through his or her DNA. In addition, the analysis could discover paternity surprises and heightened possibility of difficult or costly medical conditions. Individuals, and the parents of children, have a right to choose who can and cannot delve into their own or their children's genetic blueprint and for what purposes.

The designation of "human subject" for biospecimens is also important given the stated goal of the proposed regulation, which is focused on genetics and biospecimens - in short, use of individually unique and impossible to de-identify DNA.

Thus, designating biospecimens as "human subjects" is and should be recognized as, a FOUNDATIONAL PRINCIPLE of federal policy protecting the rights of human subjects.

Although CCHF has significant concerns about other provisions of the proposed rule (as identified and discussed in our previously submitted comment), we are very supportive of the "human subjects" designation for all biospecimens and ask that this important designation be retained in the final rule.

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