fact sheet

Research Involving Newborn Blood Spots

A new provision of federal law requires prior informed consent for certain research conducted using any newborn blood spot collected after March 17, 2015.

Infants born in the United States are screened immediately after birth for over 30 rare conditions that could pose serious or even deadly risks in the first weeks or months of life. This process involves taking a few drops of blood from the infant's heel, which are then sent for testing. In some states this sample, known as the newborn dried blood spot, is preserved for months or years. During that time it may be used for a variety of purposes, including quality assurance testing for laboratory equipment, development of new newborn screening tests, and other approved forms of research.

During consideration of the Newborn Screening Saves Lives Reauthorization Act (Public Law 113-240), an amendment was added that requires prior informed consent to be obtained before any newborn blood spot may be used in federally-funded research. The amendment has three major provisions:

- All newborn dried blood spots are now deemed to be identifiable, and therefore considered "human subjects" for the purposes of the Common Rule, the federal regulations that oversee all research studies involving people. As such, prior informed consent will be required for the use of dried blood spots in federally-funded research.
- This requirement only applies to newborn dried blood spots collected after March 17, 2015.
- Recognizing that the Common Rule is currently undergoing revision, the Administration is required to issue its proposed updates by June 16, 2015 and the final version by December 16, 2016. The final version of the Common Rule will then apply – superseding the amendment.

The requirement for informed consent applies only to research funded by certain federal agencies, such as the National Institutes of Health and the Centers for Disease Control and Prevention. It does not apply to research funded directly by states or by private individuals, foundations or institutions unless those entities also require funded studies to adhere to the Common Rule.

Discussions are currently ongoing about the interpretation of this new regulation and the best ways to consider obtaining informed consent for research involving newborn blood spots. Many states are now considering whether they may be required to put in place consent processes as part of their newborn screening programs. It is unclear, however, whether the Common Rule revisions will differ significantly from the amendment's requirements, and states may be reluctant to dedicate substantial effort to a consent process only to have to change it less than two years later.

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