Newborn Dried Blood Spots & Human Subject Research

On December 18, 2014 the Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240), an extension of the Newborn Screening Saves Lives Act of 2008 was signed into law.

The law, **effective March 16th**, applies to HHS-funded research that specifically involves the use of newborn dried blood spots. UCI applies this law to all research regardless of the source of funding.

The law includes two significant changes that apply to research with newborn dried blood spots.

- **Requires that all HHS-funded research using newborn dried spots be considered human subjects research (*and require submission of an IRB protocol for prospective IRB review*) regardless of whether the specimens are identifiable.**

- **Eliminates the ability of the IRB to waive informed consent under 45 CFR 46.116(c) and 116(d) for research involving newborn dried blood spots. *An IRB cannot approve the alteration or waiver of any elements of consent nor the requirement to obtain consent.***

Researchers currently using newborn dried blood spots for research must submit for IRB review and approval or modify their existing protocol, as necessary, to include an informed consent process.

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Link to summary of law: https://www.congress.gov/bill/113th-congress/house-bill/1281/all-info