Background

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 bill includes an amendment addressing research uses of newborn dried blood spots. The law includes two significant changes to the human subjects regulations as they apply to research with newborn dried blood spots.

First, the law requires that all research funded pursuant to the Public Health Service Act using newborn dried spots be considered human subjects research regardless of whether the specimens are identifiable.

Second, the law 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.

This law went into effect Monday, March 16, 2015. Note that this law applies only to HHS funded research that specifically involves the use of newborn dried blood spots.

TEXT OF SEC. 12. INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH:

(a) IN GENERAL.—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.

(b) EFFECTIVE DATE.—Subsection (a) shall apply only to new-born dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act.