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Colorado Multiple Institutional Review Board
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Date: August 22, 2013

Title: NewSTEPs (Newborn Screening Technical assistance and Evaluation Program) National Data Repository

Principal Investigators: Marci Sontag, PhD; Yvonne Kellar-Guenther, PhD
COMIRB Number: 13-2322

Sponsor: Health Resources and Services Administration/DHHS

Dear Drs. Sontag and Kellar-Guenther:

I would like to take this opportunity to acknowledge the hard work and effort you invested in understanding the regulatory issues surrounding your proposal for the NewSTEPs National Data Repository. You proactively sought COMIRB's guidance on whether IRB review was appropriate, given the design of this repository. In doing so, we took into account input from the Health Resources and Services Administration (HRSA), as well as the Office of Human Research Protections (OHRP).

Ultimately, it was determined that you are not engaged in human subject research. This determination was made because source data submitted from each state will be collected by a contracted data manager that is not engaged in the research by OHRP guidance; the data you receive from this data manager will not contain sufficient information to render the data identifiable by you. There are additional assurances that no identifiers will be released from states to the data manager, or from the data manager to you. Receipt of the data in this form helps to safeguard the privacy of the individuals from which it is derived. Additionally, each state that provides data to you is also not engaged in the research conducted by this protocol; under OHRP guidance on engagement, an institution whose employees or agents only release data (identifiable or not), to investigators at another institution, is not engaged in the investigators' research.

The regulatory issues involved in this study are complex. I know that this process of dissecting the issues and communicating with the different regulatory agencies delayed the start of your project, through no fault of your own, by several months. However, such thoughtful consideration of the issues helps ensure that your project is conducted in as safe, ethical, and compliant a manner as possible.

Best wishes for this important and interesting project,

Warren Capell, MD
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