
From: Stanbury, Martha (DHHS)
Sent: Wednesday, December 16, 2015 11:13 AM
To: Scott, Robert L. (DHHS)
Subject: FW: For your review (Hurley amendment)
Attachments: HIPAA waiver Hanna-Attisha 100115.pdf

I discussed this with Linda and I will try to write a justification for Mona and then have her review it.

From: MDHHS-IRB
Sent: Tuesday, December 15, 2015 4:36 PM
To: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>
Cc: Stanbury, Martha (DHHS) <stanburym@michigan.gov>
Subject: RE: For your review (Hurley amendment)

Hello Bob and Martha,

I want to send a note right away as I'm actually not sure this proposed revision is as straight forward as I thought it might be earlier (when I spoke with Martha). This IRB application was approved while thinking of this research as retrospective and involving data that had already been collected. Our IRB approved of the research with a waiver of the requirement for informed consent and a waiver of authorization for the Department to disclose protected health information to Hurley. The justification that permitted approval of those waivers (attached) included the following language:

"This study could not be practically conducted without Waiver of Authorization. The number of subjects would be greatly reduced if authorization was not waived for several reasons:

- 1) At best, possibly 75% of Flint children (and even less non-Flint children) have their labs processed at Hurley.
- 2) Of the patients whose labs were processed at Hurley, the contact information on file is often outdated or wrong.
- 3) Finally, a considerable percentage of subjects may not return calls/contacts even if the information on file was correct for them.

It is critical for this issue that we have the most data to get an accurate assessment of the impact of the water change on children's lead levels. This will help to determine risk and prioritize response. A biased sample may make any issues seem worse or better than the actual situation.

{A greatly reduced sample size would also lead to power issues with the analysis as the sample size with authorization would likely not be adequate for the analysis considering the percentage of children with elevated blood levels.}"

This language doesn't clearly support a waiver that pertains to prospective data collection. Although the issue of a biased sample may still be compelling, problems with contact information being outdated or wrong are not applicable if the potential to interact with subjects at the time of lead testing is present (that is, if the test hasn't occurred yet).

This isn't to say that a waiver of informed consent or a waiver of authorization to disclose protected health information isn't possible, but a new justification that accounts for the fact that the desired data is now to be collected prospectively is necessary. Our IRB requests that the attached document be updated to reflect this change in the research. It appears that for potentially 75% of subjects, the researcher/her institution will have an opportunity at the time blood is sampled to obtain informed consent and authorization from Hurley patients (or parents) for the use of the test result and other patient information (address specifically) in research. If a consent process is appropriate, one should be

proposed. Alternatively, a justification for why that can't occur, and/or why MDHHS must still provide identifiable data to the researcher without authorization from subjects is needed for the research to proceed.

I'm available and very willing to discuss any questions related to this. I certainly understand the interest in making data available to study this important issue. I'm also sensitive that children involved in this research have rights under the Common Rule regulations/HIPAA that prohibit the use of their identifiable information in research without consent of a parent, or without an approved waiver of the requirement for informed consent. Aside from having the researcher respond with an informed consent proposal or a revised version of the attached document, let me know if you have questions or concerns at this point.

Thank you,
-Ian

Ian A. Horste, MPH
Institutional Review Board Administrator/Chair
Michigan Department of Health and Human Services
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From: Scott, Robert L. (DHHS)
Sent: Tuesday, December 15, 2015 10:59 AM
To: MDHHS-IRB <MDHHS-IRB@michigan.gov>
Cc: Stanbury, Martha (DHHS) <stanburym@michigan.gov>
Subject: For your review (Hurley amendment)

Ian,

Please see attached.

Thanks,
Bob

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