authorization during follow-up contact with subjects (presumably contact information for subjects won't be as likely to change in the matter of days following a test as it might over the course of years as was discussed in the approved waiver request for the retrospective data).

b. It is not clear what sample size is needed for the researcher to conduct the proposed analysis. The argument that a sample that excludes the 25% of children not tested at Hurley would bias study results would be better supported with a routine power analysis documenting that greater than 75% response rate is needed. The current justification includes a claim that population-level data is required. Given the relative rarity of elevated blood lead levels among the general population, it appears reasonable that a somewhat large sample will be needed to provide accurate characterizations of differing rates by geography and over a certain time scale, but to state that the analysis couldn't be conducted without population level data is certainly not supported in the documentation provided. A discussion that demonstrates the need for a minimum response rate and additional proof that such a response would not be achieved if authorization from each subject was required would be helpful in documenting why the research cannot be conducted without an approved waiver.

Thank you for considering these points. I look forward to a response addressing these concerns. Regards,
-Ian

Ian A. Horste, MPH
Institutional Review Board Administrator/Chair
Michigan Department of Health and Human Services
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From: Stanbury, Martha (DHHS)
Sent: Friday, December 18, 2015 1:23 PM
To: MDHHS-IRB <MDHHS-IRB@michigan.gov>
Cc: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>
Subject: RE: For your review (Hurley amendment)

Hello Ian: Attached is the HIPAA waiver form amended that has been signed by Dr. Hanna-Attisha, which hopefully addresses your concerns. Please let Bob and me know. Many thanks, Martha

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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

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