From: Stanbury, Martha (DHHS)
Sent: Monday, December 21, 2015 2:56 PM
To: MDHHS-IRB <MDHHS-IRB@michigan.gov>
Cc: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>; Dykema, Linda D. (DHHS) <DykemaL@michigan.gov>; Mona Hanna-Attisha <MHanna1@hurleymc.com>
Subject: RE: For your review (Hurley amendment)

Hello Ian: Thank you for your comments. In the attached document I have prepared some remarks that hopefully address your concerns. I look forward to hearing from you on this. Regards, Martha

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From: MDHHS-IRB
Sent: Monday, December 21, 2015 10:54 AM
To: Stanbury, Martha (DHHS) <stanburym@michigan.gov>
Cc: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>
Subject: RE: For your review (Hurley amendment)

Hello Martha,

Thanks to you and to Dr. Hanna-Attisha for the very prompt response to my initial inquiry. I appreciate the comments provided. It does not appear (at this point) the threshold for impracticability of obtaining authorization and therefore the threshold for approval of a prospective waiver of authorization has been met. I'm hopeful the following questions will be helpful in thinking through alternative approaches to this research or the details of the waiver request:

1. Is it not possible for MDHHS to receive data from Hurley that allows MDHHS to perform the removal of duplicate test results? If MDHHS (the non-research entity and the entity holding the more inclusive data set) received information from Hurley that allowed for duplicate data to be screened out of prospective data transfers, MDHHS would appear to only need to send address, age, test date and result (that is, less protected health information than proposed) to the researchers. This would minimize the risk of providing additional identifying information (Child ID Number) about non-Hurley patients to the researchers. Understanding that the retrospective data transfer included a large number of records that perhaps prohibited MDHHS from performing this function prior to data transfer, it appears any subsequent data exchanges will be relatively small in comparison. Minimization of risks is important to IRB approval generally. If MDHHS involvement at this level is not possible, please document that.
2. There are two weaknesses with the current justification for the waiver related to the impracticability of conducting the research without the waiver.
    a. The case is made that obtaining authorization would be difficult, but it is not clear this meets the threshold of impracticability. The researcher does not indicate how many potential subjects will be included in the prospective research. If there are hundreds of subjects being tested each day, it would seem more likely that coordination across Hurley practitioners and/or others would be difficult to the point of impossible. If there are relatively few tests performed per day, then coordination typical of routine clinical research should not be an issue. Also, the opportunity to obtain authorization does not appear limited to the time of the testing. It appears there is additional opportunity to obtain

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

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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