From: MDHHS-IRB
Sent: Tuesday, December 22, 2015 1:47 PM
To: Stanbury, Martha (DHHS)
Cc: Scott, Robert L. (DHHS);Dykema, Linda D. (DHHS);Mona Hanna-Attisha
Subject: RE: For your review (Hurley amendment)
Attachments: Study Proposal IRB BLL MHA revised 10 1 15.docx

Hello Martha,

Thank you again for the prompt and thorough response to the IRB comments. Your most recent e-mail was very helpful to my understanding of the proposed revision. What I think has caused confusion to this point, is that the originally approved study protocol (submitted to the MDHHS IRB on 10/1/2015) included only a limited analysis of pediatric blood lead data. In fact, a power analysis had been performed with the initial proposal indicating only a relatively small population sample would be required for the researchers to address the proposed aims. Because no revised protocol is yet available to me, it was my understanding with this revision that the scope of the research proposed had only changed with respect to the time frame to be studied.

It appears, however, given the description provided with your last e-mail, that the researchers now intend to perform a much more detailed characterization of the pediatric population in Flint. The request for a prospective waiver of informed consent that has been submitted reads much more appropriately for a descriptive study. I think what would be most helpful here, and what would likely allow our board to view a waiver request positively, is a revised research protocol that captures the new design of the research to be conducted at Hurley Medical Center.

I've attached the protocol that is currently approved in case that is a helpful reference. Please note that our IRB acknowledges the minimal risk nature of this proposal, we agree that there is the potential for benefit to this research, and we think the data security measures proposed should protect the data requested. At this point, we simply want to verify that the privacy rights of subjects under HIPAA are appropriately respected. If it is not necessary to disclose protected health information for this research without authorization from subjects, then we don't want to violate that right. If it is necessary to disclose protected health information without authorization for this research to occur, then we can approve the waiver and this revision to the research. I look forward to reviewing an updated research protocol. Do not hesitate to contact me with any questions or concerns.

Thank you,
-Ian

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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