## Peeler, Nancy (DHHS)

**From:** Scott, Robert L. (DCH)
**Sent:** Wednesday, September 30, 2015 2:36 PM
**To:** Travis, Rashmi (DCH)
**Cc:** Colston, Leslie (DCH); Fink, Brenda (DCH); Peeler, Nancy (DCH)
**Subject:** FW: IRB application and related documents (2nd of two emails I'm forwarding)

FYI

**From:** Scott, Robert L. (DCH)
**Sent:** Wednesday, September 30, 2015 12:59 PM
**To:** Jenny LaChance <JLachan1@hurleymc.com>
**Cc:** 'Mona Hanna-Attisha' <MHanna1@hurleymc.com>
**Subject:** FW: IRB application and related documents

Please see MDHHS IRB's comments below. Regarding the first #1 below, that's partly my fault for missing the reference to MCIR in your protocol. Did I ever explain that MCIR does not store any blood lead results? They are stored in the MDHHS Data Warehouse. MCIR then links to the Warehouse and *displays* any records found for a given child. Along that line, I changed your reference to MCIR in the DUA to read "MDHHS Childhood Lead Poisoning Prevention Program database" (which feeds data to the Warehouse), but I didn't catch it in your protocol. So, please make that change in your protocol—and while you're at it, you might as well change the list of attributes requested to match the DUA: "Child ID number, date of birth, date of blood draw, address with zip code, blood lead level, and specimen type." I assume this means you'll have to loop back through Hurley's IRB.

Regarding the first #2 below, please note that I had copied and pasted from your HIPAA Waiver to your DUA Section 2: Agreement Conditions, #3. (I had asked for this info in one of my emails, but you must have missed it—the request was sort of buried among other comments.)

Regarding that first #2 and the second #1,2,3, please make whatever changes you think appropriate to address Ian's concerns. It's probably best if I get out of the way, and not try to interpret for you. If you have questions about Ian's concerns, please feel free to correspond with him directly and CC me.

Bob

**From:** MDHHS-IRB
**Sent:** Wednesday, September 30, 2015 11:41 AM
**To:** Scott, Robert L. (DCH) <ScottR9@michigan.gov>
**Cc:** Boes, Colin (DCH) <BoesC1@michigan.gov>
**Subject:** RE: IRB application and related documents

Hello Bob,

Thank you for your work in coordinating submission of these IRB application documents, as well as the draft Data Use Agreement which Colin has shared with me. Colin and I have touched base and we have some questions related to the application generally and the request for a Waiver of the Requirements for Authorization.

There is some confusion in the IRB application to Hurley, and I'm guessing this is likely due to the IRB application having been written before the specifics of data sharing (as appear addressed thoroughly in the DUA) were worked out. To make sure we understand what is proposed, however, I'm hopeful you/the researchers can speak to the following:

1. The IRB application speaks to data being obtained from MCIR while the DUA speaks to data being obtained from the Childhood Lead Poisoning Prevention Program database. Please clarify the source and form of the data to be provided from MDHHS. Notably, will records be obtained via provider access to MCIR? Or will data originating from MDHHS sources be prepared for disclosure exclusively by MDHHS staff?
2. Although both the IRB application and DUA speak to the Child ID number being destroyed at the earliest possible time point (once duplicate entries have been removed), it is unclear whether the same is true for other potentially identifying information (address, birth date, testing date, etc.). The IRB application appears to suggest these identifying fields will be maintained, where the data use agreement appears to indicate that masking of these fields (removing dates and replacing with age and pre/post conversion field and masking address by geocoding to affected vs. not affected geography) is possible and will be conducted as early as possible. Please clarify the actual plan for the handling of identifiable information.

With respect to the requested Waiver of Authorization, the following clarifications would be helpful:

1. Please justify why address should remain associated with the testing data through dissemination and peer review (rather than a less specific affected area vs. non-affected area field). If it is necessary to maintain address (or any other personally identifiable information) please clarify how that information might be used.
2. Is only the minimum necessary PHI being requested for disclosure? Might some of the masking (dates and or address) be performed prior to disclosure? The item asking: "Describe why the study could not practicably be conducted without access to and use of the protected health information (PHI) requested" should address this. It appears that the researchers (as the only entity with access to data from all of the sources) will need a mechanisms to remove duplicate entries, but it is not clear why some of the other identifying information needs to be disclosed to the researchers; please clarify.
3. The item asking "Describe why the study could not practicably be conducted without this Waiver of Authorization" is not properly addressed. In essence this item is asking why it is not possible to obtain authorization from subjects of this research for the disclosure of their protected health information to the researchers. Because many of the subjects will be Hurley Medical Center patients, it appears there may be an opportunity for outreach to obtain authorization. The waiver request should document if there might be problems obtaining accurate contact information, or if anticipated response rate might lead to a sample size without adequate power, or if there are other barriers to asking permission for the use of the data requested before it is disclosed. Additional information will be appreciated.

If you or the researchers have concerns on any of these questions, please do not hesitate to let me know. Regards,
-Ian

Ian A. Horste, MPH
Institutional Review Board Administrator/Chair
Michigan Department of Health and Human Services
517-241-0806
www.michigan.gov/irb



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**From:** Scott, Robert L. (DCH)
**Sent:** Tuesday, September 29, 2015 4:42 PM
**To:** MDHHS-IRB
**Subject:** IRB application and related documents