Marc,

Please see Colin's (Legal Affairs) comments below. I apologize for not passing it along yesterday—the day got away from me. I clearly have a lot to learn—I made changes to your document thinking it was a slam-dunk as de-identified, but was wrong, as indicated below.

Please make changes to your DCH-1294 as directed by Colin's comments, and re-submit to me, still no signature.

Thanks,
Bob

From: Boes, Colin (DCH)
Sent: Friday, September 11, 2015 2:08 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Horste, Ian (DCH) <Horstei@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Robert,

Here are my comments regarding this DUA. Please feel free to give me a call if you have any questions. As I indicate below, we also need to see about whether our IRB needs to be involved.

1. I want to know more about the study that is being recreated in item 1. The attached protocol seems to discuss more about the study of the water samples, not the blood lead data. Saying that the researcher wants to verify the claim of MDEQ is not sufficient. It does not have to be a great deal longer, but it should explain what the intended use of the blood lead data is.

   It is also important to know exactly how it will be used for research in order to justify the release not just under HIPAA, but also under R 325.9086 pertaining to the confidentiality of blood lead test reports. It must be for the "If necessary for the purpose of research designed to develop or contribute to generalizable knowledge, with documented approval by the department's institutional review board." R 325.9086(2)(e). I am not sure how Ian would handle this, given the language in the rule that seems to require IRB approval.

2. Tying in with 1. above, telling us that the analysis will be similar to some other study is insufficient. This section should tell us how the data will be used and disclosed, how many people (research team) might have access, what formats it might be used in and other similar information. The attached research protocol, as noted above, does not get into sufficient detail regarding exactly how our blood lead data will be used and how its use will be restricted.

   I also need to know more about how the data will be secured on their end, how it will be handled, by who, and what will be done with it when it is no longer needed for their study.

3. The researcher indicates this data will be deidentified, but then goes on to ask for a number of identifiers that make the data identifiable, including county, city, and birth date of the child. In order for data to be deidentified (short of the statistical analysis method which would have to be documented and shown to us), it must not contain any geographic subdivision smaller than state. 45 CFR 164.414(b)(2)(i)(B).

Additionally, all elements of dates related to the individual must not be included, which includes birth date. 45 CFR 164.414(b)(2)(i)(C). Therefore, the researcher must follow protocols for identifiable data, which may include requesting a waiver of informed consent from the IRB.

The researcher could possibly obtain the data requested as a limited data set without a waiver I believe (though we still would want to run it by the IRB). If this is the case, item 3.b. should be changed to "Limited Data Set."

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From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:44 PM
To: Boes, Colin (DCH)
Subject: RE: New DCH-1294, time-sensitive

Thanks. I was told by a colleague of mine that Ian is expected back on Monday (I hope she was right).

I think the researcher is hoping for a turn-around with a week or so, but I'm sure he knows he can't make (and hasn't made) demands. I'll check with him about an IRB.

From: Boes, Colin (DCH)
Sent: Friday, September 11, 2015 1:33 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Robert, thank you for letting me know about the time-sensitivity. I will do my best to get this turned around as soon as I can. Since this involves research you may wish to send it the IRB as well and let them know about the urgency. How soon do you think they were hoping to get it back? A few weeks? Shorter? I ask because our IRB director Ian is out of the office until at least next week (I cannot remember exactly how long he is out).

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From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:26 PM
To: Boes, Colin (DCH)
Subject: New DCH-1294, time-sensitive

Colin,

Please see attached DUA and related proposal. I'm asking for a reasonably-quick turn-around on this request for de-identified data, if possible given your schedule. I've pasted Professor Edwards' comments below: