

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) <ScottIR9@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, Collin (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:

"Yes, I think there is clearly some urgency to the situation.

MDEQ has publicly stated that your blood lead records, are showing that there is no public health concern for residents in Flint.

The levels of lead in Flint water, that we are finding in our water sampling, are certainly in a range that can cause childhood lead poisoning.

Indeed, one child has already, likely been lead poisoned from exposure to high lead in water.

I think the fact that you already have other teams working on these records, indicates a high level of interest, and urgency.

Congressional interest in the safety of the water is also very high, and this will be an important issue in deciding options for treating the water, in the weeks and months ahead."

Thanks,
Bob

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