

Scott, Robert L. (DHHS)

From: Marc Edwards <edwardsm@vt.edu>
Sent: Monday, September 21, 2015 1:20 PM
To: Scott, Robert L. (DCH)
Subject: RE: New DCH-1294, time-sensitive

I am not sure how we can proceed. The Age in months would be fine.

But is it true that providing zip code level analysis, if you combine 48503 and 48504 into a "high risk" Flint area (50000+ residents), and the rest into a "low risk" Flint area, is by definition identified?

In that case, do I need to do an IRB, with my institution, to obtain data from you identified at the zip code level, and then get approval for that? Data would only be handled by me on my computer which is password protected.

If I get our IRB approval for my study with only zip code identified, are you then allowed to share that data (with zip code identified) with me?

Ultimately, zip code data will be combined into EBL% within that zip code, and there is no intention to look at individuals except by age in months.

I am not sure how to proceed.

Marc

From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Tuesday, September 15, 2015 5:10 PM
To: Marc Edwards
Subject: RE: New DCH-1294, time-sensitive

I can certainly provide age in years instead of date of birth, although either one would be acceptable according to this link I found:

http://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/limited_data_set.html

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Tuesday, September 15, 2015 4:58 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Can you tell me how I can do a limited dataset? Can I just have the age in years, for example?

Thanks so much!

Marc

From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Tuesday, September 15, 2015 9:21 AM
To: Marc Edwards
Subject: FW: New DCH-1294, time-sensitive

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 I. 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).