

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, September 29, 2015 3:13 PM
To: Peeler, Nancy (DCH)
Subject: RE: data request

OK

-----Original Message-----

From: Peeler, Nancy (DCH)
Sent: Tuesday, September 29, 2015 3:12 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: data request

Just had email from Dr. Wells about some data, I need to connect with you ASAP and email back to her. Will forward the email, then come find you after this meeting. Appreciate anything you can do to start looking into the question quickly.

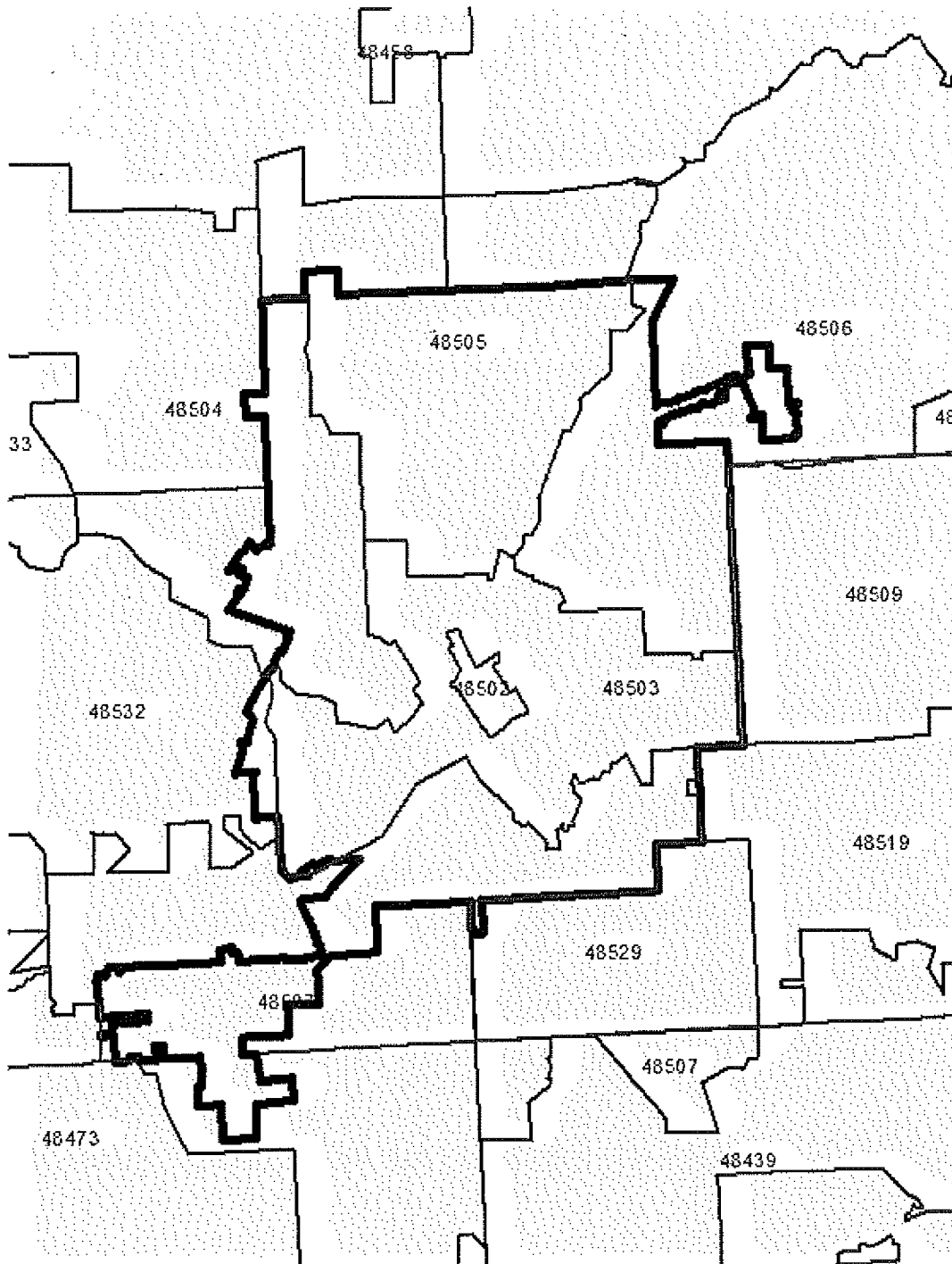
N

Sent from my iPad

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, September 29, 2015 4:17 PM
To: Peeler, Nancy (DCH)
Cc: Fink, Brenda (DCH)
Subject: RE: Public Health Advisory

Hurley said they used zips 48501 through 48507. Yes, 48504 through 48507 all cross the city/township lines. Not sure how well this screenshot shows it (black outline is Flint; blue lines are zips). Cristin was going to geocode to the census block group—those will not cross city/township lines.



From: Peeler, Nancy (DCH)
Sent: Tuesday, September 29, 2015 4:04 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Fink, Brenda (DCH) <FinkB@michigan.gov>
Subject: FW: Public Health Advisory
Importance: High

Forwarding, FYI. The analysis is now in the hands of Epi, so out of our realm.

Just curious – Bob, what were the zip codes Hurley used, and do they cross over into the townships, or are they completely within city boundaries?

From: Lasher, GERALYN (DCH)
Sent: Tuesday, September 29, 2015 12:06 PM
To: Wells, Eden (DCH); Miller, Corinne (DCH); Moran, Susan (DCH); Robinson, Mikelle (DCH); Dykema, Linda D. (DCH); LyonCallo, Sarah (DCH); Hertel, Elizabeth (DCH); Peeler, Nancy (DCH); Travis, Rashmi (DCH); Miller, Mark (DCH)
Cc: Minicuci, Angela (DCH); Eisner, Jennifer (DCH); Grijalva, Nancy (DCH)
Subject: FW: Public Health Advisory
Importance: High

And Genesee County and the Genesee County Health Department, have just issued the attached public health advisory and on the final paragraph it says:

Recent data provided by Hurley Hospital researchers has indicated that a significant increase in blood lead levels has occurred in children since the switch to Flint River water. The county Health Officer has requested that the Michigan Department of Health and Human Services (MDHHS) provide to the County specific data to support its claim that state data is more comprehensive and does not show a significant increase. To date, the MDHHS has failed to confirm the geographic area included in their findings. We want to assure the state data is specific to the boundaries of the City of Flint, and not Flint addresses which would include addresses in areas outside of the City of Flint. These areas, such as Flint Township, that obtain their water from the Detroit Water Authority and would, therefore, not be representative of Flint River water as the water source. The County is prepared to take further action if the State fails to provide the requested data by September 30, 2015. Further action could include a request for outside independent evaluation of the data and to declare a Public Health Emergency in Flint.

I understand that we are still reviewing the data—but the county has basically issued a ransom date that they want this information by tomorrow.

Eden—please coordinate an answer so Nick can walk into the 1:00 p.m. meeting prepared on this.

From: Minicuci, Angela (DCH)
Sent: Tuesday, September 29, 2015 11:59 AM
To: Lasher, GERALYN (DCH) <lasherg@michigan.gov>
Subject: FW: Public Health Advisory
Importance: High

Last paragraph, last page.

Angela

From: Sandlin, Mary [<mailto:MSANDLIN@gchd.us>]
Sent: Tuesday, September 29, 2015 11:55 AM
Subject: Public Health Advisory
Importance: High

Mary E. Sandlin
 Clerical Coordinator
 Genesee County Health Department
 630 S. Saginaw Street, Suite 4
 Flint, MI 48502-1540
 (810) 257-3812 FAX: (810) 257-3147
msandlin@gchd.us



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For a copy of the Health Department's Notice of Information Practices, contact the Health Department or visit the Health Department's website at <http://www.gchd.us>

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Wednesday, September 30, 2015 10:25 AM
To: Peeler, Nancy (DCH)
Subject: RE: For Wednesday - 3 things

Will do, and yes we are! ☺

From: Peeler, Nancy (DCH)
Sent: Tuesday, September 29, 2015 6:07 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: For Wednesday - 3 things
Importance: High

1. I think we may need to respond to a request from Geralyn to re-run our charts we provided, limiting it to children <6 years of age. Waiting for confirmation.
2. I feel another request coming– can you run the most up-to-date lead testing rates for our top 10 (11) counties, e.g. those that receive Prevention grants – I think Budget is going to ask us why Genesee doesn't get an Intervention grant, and we'll want to show them updated numbers (that they aren't in the top 3). I may be wrong, but trying to anticipate.
3. And, amidst all else - can you take a peek – is Genesee billing Medicaid for any lead services?

I guess we are collecting ample evidence for CDC that we use our surveillance data...

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Wednesday, September 30, 2015 2:35 PM
To: Travis, Rashmi (DCH)
Cc: Colston, Leslie (DCH); Fink, Brenda (DCH); Peeler, Nancy (DCH)
Subject: FW: State data - Dr. Mona Hanna-Attisha (1st of two emails I'm forwarding)
Attachments: DCH-1294 Hanna-Attisha 9 30 15.doc

Rashmi,

FYI, I'm forwarding two emails I've sent to Dr. Hanna-Attisha and Ms. LaChance today, regarding the Data Use Agreement and the IRB review application for their data request.

Please let me know if you have questions.

Thanks,
 Bob Scott

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

From: Scott, Robert L. (DCH)
Sent: Wednesday, September 30, 2015 10:47 AM
To: 'Mona Hanna-Attisha' <MHanna1@hurleymc.com>
Cc: Jenny LaChance <JLachan1@hurleymc.com>
Subject: RE: State data - Dr. Mona Hanna-Attisha

Mona,

The attached DUA has been approved by MDHHS Legal. Please sign, scan and return to me as a PDF.

No word yet on the IRB review.

Thanks,
 Bob

From: Mona Hanna-Attisha [<mailto:MHanna1@hurleymc.com>]
Sent: Tuesday, September 29, 2015 4:44 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Jenny LaChance <JLachan1@hurleymc.com>
Subject: Re: State data - Dr. Mona Hanna-Attisha

Bob, Do you have a time estimate on when we will receive the data? The first time I asked our county health dept for this data was Aug 27 and they eventually realized they didn't have the ability to pull such data and then the first time I asked you for the data was mid September. I recognize this has nothing to do with you, but it's been a bit frustrating. Just hoping for a quick turn around.

Thanks.

Mona Hanna-Attisha MD MPH FAAP
 Director, Pediatric Residency Program
 Hurley Children's Hospital
 Michigan State University

On Sep 29, 2015, at 4:34 PM, Scott, Robert L. (DCH) <ScottR9@michigan.gov> wrote:

Got 'em, thanks. I've sent your Data Use Agreement to Legal for review, and will send all four IRB-related documents to our IRB.

From: Jenny LaChance [<mailto:JLachan1@hurleymc.com>]
Sent: Tuesday, September 29, 2015 4:32 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Mona Hanna-Attisha <MHanna1@hurleymc.com>
Subject: RE: State data - Dr. Mona Hanna-Attisha

Hi Bob,

Please see attached the HIPAA waiver form signed by Mona (PI) and the most recent IRB proposal (note the highlighted areas are based on a requirement from our IRB). If anything else is needed, please just let me know.

Kind regards,
 Jenny

From: Scott, Robert L. (DCH) [ScottR9@michigan.gov]
Sent: Tuesday, September 29, 2015 4:06 PM
To: Jenny LaChance
Cc: Mona Hanna-Attisha
Subject: RE: State data - Dr. Mona Hanna-Attisha

Jenny,

Please send the study protocol that you submitted to the Hurley IRB. I have your approval letter, thanks, but the MDHHS IRB will want to see the protocol as well.

While you're at it, might as well, sign, scan and resend the HIPAA Waiver form (attached)—I assume it won't need any edits.

Thanks,
 Bob

From: Jenny LaChance [<mailto:JLachan1@hurleymc.com>]
Sent: Friday, September 25, 2015 5:03 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Mona Hanna-Attisha <MHanna1@hurleymc.com>
Subject: RE: State data - Dr. Mona Hanna-Attisha

Hi Bob,

Please see attached the revised application and draft HIPAA waiver form. Please let me know if any changes are needed. (Does Mona need to sign the Waiver now or would that be after it is

reviewed?) I'm happy to make any changes.

Thanks!
Jenny

From: Jenny LaChance
Sent: Friday, September 25, 2015 4:29 PM
To: Scott, Robert L. (DCH); Mona Hanna-Attisha
Subject: RE: State data - Dr. Mona Hanna-Attisha

Hi Bob,

Thank you! I am revising the original application and completing the HIPAA waiver form now. I will send to you soon.

Thanks again,
Jenny

From: Scott, Robert L. (DCH) [ScottR9@michigan.gov]
Sent: Friday, September 25, 2015 4:09 PM
To: Jenny LaChance; Mona Hanna-Attisha
Subject: RE: State data - Dr. Mona Hanna-Attisha

Jenny,

As long as this request is for "research," then I don't think it will be a problem to provide addresses. You're correct, it would then be considered "identifiable." One thing that might slow it down—I believe you'd have to go back to Hurley's IRB and get approval for the change.

Bob

From: Jenny LaChance [<mailto:JLachan1@hurleymc.com>]
Sent: Friday, September 25, 2015 4:05 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Mona Hanna-Attisha <MHanna1@hurleymc.com>
Subject: State data - Dr. Mona Hanna-Attisha

Hi Bob,

My name is Jenny LaChance, and I have been working with Mona on the data. We are now doing in depth GIS analysis, which involves actual address (beyond zipcode). Would adding actual address slow down the request for the State data? I believe this would not longer be a limited data set. Any advice or guidance would be truly appreciated.

Thank you so much!
Jenny

DATA USE AND NON-DISCLOSURE AGREEMENT CONCERNING PROTECTED HEALTH INFORMATION OR OTHER CONFIDENTIAL INFORMATION

Michigan Department of Health and Human Services

Project Title: Analysis of Pediatric Blood Lead Levels in Flint, MI

Data Recipient: Mona Hanna-Attisha, MD MPH and co investigators Jenny LaChance MS and Richard Sadler PhD

Organization: Hurley Medical Center

Address: One Hurley Plaza
Flint, MI 48503

Phone: 810-262-7257 **e-mail:** mhanna1@hurleymc.com

In accordance with this agreement, data are provided by the Michigan Department of Health and Human Services (MDHHS), **Family, Maternal and Child Health/Family and Community Health** on **September/October 2015** to the Data Recipient.

The parties agree to the provisions specified in this Agreement, the Health Insurance Portability and Accountability Act (HIPAA), and all other applicable public health, research, and confidentiality laws.

SECTION 1: DATA SOURCE, PURPOSE, USE, DESCRIPTION, APPROVAL (IF HUMAN SUBJECT RESEARCH)

What is the Source of the Requested Data? (e.g., Vital Records, Health Statistics, Cancer Surveillance, Medicaid, etc.)

MDHHS Childhood Lead Poisoning Prevention Program database

What is the Data Recipient's Purpose for, and Specific Use of, the Data?

1. Describe why these data are requested (e.g., Research, Statistics, Public Health, Health Care Operations, Administration of the Medicaid Program).

These data are being requested for two reasons: the primary purpose is related to public health. We are looking at the impact so that measures can be implemented to address any increase in children with elevated blood levels. The data is also being for research purposes so our findings can be shared with other communities.

2. Describe how the data will be used/disclosed, or incorporate by reference and attach a copy of the research protocol, work plan, or request letter that details the purpose and use of data, etc.

Data for SPSS will be deidentified once 1) one value per person has been selected, 2) whether or not they live in the higher risk part of Flint for lead has been coded, and 3) the timing of when they had their lead level (pre/post) has been determined. GIS analysis will use address but will not include any other PHI identifiers.

Data will be saved only on encrypted zip drives or secure hospital computers located in personal office of one of the researchers. Only the 3 researchers directly involved with study will have any access to data. Encrypted zip drives will be kept secure with a researcher or in a locked office at all times. Once identifiable data is not needed, files with identifiable information will be destroyed.

3. Describe the data requested indicating amount, type, by what medium the data will be provided, and whether the data recipient is granted access to the data warehouse or state archives.

Data Overview Description

- a. Specify the data elements (e.g., age, gender, etc.) and time periods (e.g., January 2003 through January 2005).

Time period: January 2013 through Sept 15, 2015; Data Elements: Child ID number, date of birth, date of blood draw, address with zip code, blood lead level, and specimen type. Gender, race and insurance type are also requested if available.

- b. Specify if the data requested is identifiable, de-identified, or a limited data set as defined by HIPAA.

Identifiable since addresses are being requested for GIS analysis

- c. Specify the medium requested (e.g., electronic, hard copy, etc.).
electronic
- d. Specify if direct access to the data warehouse or state archives is requested.
Not unless necessary for this request of data

Research Project: Complete this box if requested data will be used for human subjects research.

Is Institutional Review Board (IRB) (human subjects research) approval required?	☒ YES ☐ NO
If YES, MDHHS Approval Number (Attach MDHHS Approval Form)	Approval Number
Is HIPAA Informed Consent/Authorization Waiver Required?	☒ YES ☐ NO
If YES, MDHHS Approval Number (if above IRB approval not required) (Attach HIPAA Waiver Authorization, if relevant.)	Approval Number

SECTION 2: AGREEMENT CONDITIONS

With regard to data provided under this agreement, the Data Recipient agrees to:

1. Use and disclose the data only in accordance with this agreement, or as otherwise required by law;
2. Limit access to these data only to those described and authorized in this agreement; *(MDHHS may require the specific identification of the person(s) or the agency/division/office that is permitted access. Identify if needed.)*
3. Use appropriate safeguards to prevent use or disclosure of the information other than as provided by this agreement; *(MDHHS sponsor may require description of the security procedures that will be in place and followed.)* Data will be kept very secure through the use of encrypted thumb drives (or on hospital secure computers in individual researchers' offices) and only seen by 3 researchers. Data will be with one of the researchers or in a locked office at all times. Identifiers will be removed for files for analysis as not needed and all identifiable data destroyed once not needed. As soon as data files and analysis are completed, files with identifiers will be destroyed. For GIS analysis, data and analysis file with address will be kept until after all work on data is complete, including dissemination and time for peer response.
4. Report to the responsible MDHHS sponsor any use or disclosure of information that is not provided for by this data use agreement;
5. Ensure that any agent(s) or subcontractor(s) who access these data agree to the same restrictions and conditions that apply to the data recipient; *(MDHHS sponsor may stipulate that release of data to a subcontractor cannot be done without the written authorization of MDHHS.)*
6. Make no attempt to identify or contact the individuals, providers, or health plans within the data provided unless approved in this agreement; *(Describe any agreed upon exceptions if needed.)*
7. Data recipient must provide MDHHS at least thirty days to review and provide comments on papers, publications, or presentations that the data recipient plans to submit for publication or presentation. Data recipient agrees that it will not publish or disseminate any protected health information, personally identifiable information, or data that might make it possible, directly or indirectly, to identify an individual. Data recipient must acknowledge the MDHHS program as appropriate (e.g., source of data, etc.), assume full responsibility for the analysis and interpretation of the data, and provide a copy of the publication or presentation to MDHHS. To the extent data recipient requires technical assistance in analyzing or interpreting the data and when such assistance goes beyond providing non-manipulated data, MDHHS reserves the right to request that these activities be considered a substantial contribution to the research being conducted and that the provision of such assistance may warrant MDHHS be considered as a research collaborator or co-author in any resulting publications or presentations;
8. Return or destroy all originals and copies of any potentially identifiable information upon completion of project, or upon request, unless otherwise approved in this agreement. This includes, but is not limited to: magnetic tape, micro disk files, paper records, etc. If not returned to the MDHHS, then the data must be destroyed; e.g., use a CD/DVD shredder to destroy CD Roms, DVDs, etc., erase floppy/zip disks using a magnet, shred paper records, clean computer hard drives with a program designed to wipe a disk by overwriting, etc.;
9. Not use the data provided to engage in any method, act, or practice which constitutes a commercial solicitation or advertisement of goods, services, or real estate to consumers; and
10. Not use the data provided as a basis for legal, administrative or other actions which may affect particular individuals or establishments as a result of their specific identification in this project.

The MDHHS may cancel this agreement with proper notice.

The unauthorized use or disclosure of confidential information is punishable by imprisonment or fine or both under state and federal laws specific to the data released.

I, the data recipient, have read, understand, and agree to the above conditions.

DATA RECIPIENT SIGNATURE:

Mona Hanna-Attisha, MD, MPH	Director, Pediatric Residency Program, Hurley Children's Hospital
Name of Responsible Data Recipient (Type or Print)	Title

Signature of Responsible Data Recipient	Date
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MDHHS SIGNATURES:**MDHHS SPONSOR**

Robert L. Scott	Departmental Specialist
Name of Responsible MDHHS Sponsor (Type or Print)	Title

Signature of Responsible MDHHS Sponsor	Date
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MDHHS RESPONSIBLE PARTY

Brenda Fink, A.C.S.W.	Director, Division of Family and Community Health
Name of MDHHS Director, Bureau Director, or Delegated Authority (Type or Print)	Title

Signature of MDHHS Director, Bureau Director, or Delegated Authority	Date
--	------

AUTHORITY: This form is acceptable to the Michigan Department of Health and Human Services as compliant with HIPAA privacy regulations, 45 CFR Parts 160 and 164 as amended.

COMPLETION: Is required if disclosure is requested.

The Michigan Department of Health and Human Services is an equal opportunity employer, services, and programs provider.

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

Please see four attachments: Abbreviated IRB app; signed HIPAA Waiver Request; Hurley IRB approval; and Study Proposal that was submitted to Hurley IRB.

A related Data Use Agreement has been sent to Colin Boes for his review.

Please let me know if you need anything else.

Thanks,
Bob

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Wednesday, September 30, 2015 5:05 PM
To: Peeler, Nancy (DCH)
Subject: Hurley

Hurley Medical Center is listed as the "Provider" on approximately half of the blood lead results we received for Flint children in 2014—I assume that pattern holds in 2015 and in recent years. Warde Medical Lab is listed as the "Laboratory" on those results. Warde reported the results to CLPPP in accordance with State law.

I can't say whether the blood specimens were a) drawn at Hurley's lab, or b) simply passed through Hurley's lab—from physician office to Hurley to Warde for analysis. As I understand it, both scenarios are common at various hospital labs.

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Thursday, October 01, 2015 8:06 AM
To: Peeler, Nancy (DHHS)
Cc: Lishinski, Karen (DHHS)
Subject: RE: Hurley -- follow up about the question on Hurley lab results

We report on testing and elevated levels annually by fiscal year for the legislature--by county/Detroit and the state. We report annually by calendar year for stakeholders and the public--by county, by several funded communities, and by ZIP code; also the Medicaid population by county. These annual reports include tables, graphs and maps to provide detailed information about the past year, as well as trends over several years. We produce other reports by request.

We used to produce similar reports by quarter, and even a special monthly report for funded health departments. But as we have lost funding and staff, and as my own time has been pulled in other directions, these other more-frequent reports have fallen away.

Child- and address-specific data continues to be provided to every local health department every week—via HHLPS on-line system, and via securely-transmitted Excel files--so that they have information on lead levels for children in their jurisdictions.

BLLs ≥ 20 are faxed to local health departments the same day we receive them. Starting a few months ago, copies of all BLLs ≥ 5 are provided to our Nurse Consultant weekly, to help her monitor elevated levels in each local jurisdiction.

From: Peeler, Nancy (DCH)
Sent: Wednesday, September 30, 2015 6:50 PM
To: Wells, Eden (DHHS) <WellsE3@michigan.gov>; Miller, Corinne (DHHS) <MillerC39@michigan.gov>; Miller, Mark (DHHS) <millerm1@michigan.gov>; LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Dykema, Linda D. (DHHS) <DykemaL@michigan.gov>; Priem, Wesley F. (DHHS) <priemw@michigan.gov>; Travis, Rashmi (DHHS) <TravisR@michigan.gov>
Cc: Fink, Brenda (DHHS) <FinkB@michigan.gov>; Scott, Robert L. (DHHS) <ScottR9@michigan.gov>
Subject: RE: Hurley -- follow up about the question on Hurley lab results

I can partially answer your question now, will get additional info from Bob and send more later.

The data flows in daily, year-round. We process several thousand test results every week. We monitor the results daily, and have an algorithm for our follow-up response, based on the blood lead level.

Because we are processing results every day, we do see some patterns if they begin to emerge, especially with the higher lead levels. We normally track and report data at health department level, county level/Detroit. We are still building our capacity and putting new procedures in place via our CDC Surveillance grant to crank out more reports/report cards, and more frequent data reports, especially with the switch in focus to levels of 5 and above (which means we are focusing on a larger number of results than just 10 and above). We develop and share out many maps, charts, graphs, and yes, do publish an annual legislative report.

We have .2 FTE Epi support (Cristin Larder), mostly for special projects and/or reports, for example, Cristin is working with us and Dr. Stan Kaplowitz from MSU to use his research to help pinpoint smaller geographic areas with higher risk, so we can better direct resources toward those areas.

Bob, can you please add more information about frequency of your analysis, and how we detect issues?

From: Wells, Eden (DCH)

Sent: Wednesday, September 30, 2015 6:24 PM

To: Peeler, Nancy (DCH); Miller, Corinne (DCH); Miller, Mark (DCH); LyonCallo, Sarah (DCH); Dykema, Linda D. (DCH); Priem, Wesley F. (DCH); Travis, Rashmi (DCH)

Subject: RE: Hurley -- follow up about the question on Hurley lab results

That sounds about right.

May I ask,, is it CLPP's usual process to collect the lead data on an ongoing basis...if so, at what level is the data usually analyzed (by Epi?) IS it daily,monthly? Quarterly? Annually? How would we normally detect/know if there is an issue in a particular locality---do you look at it at county level or smaller when you peruse your data? This question may arise...

E

From: Peeler, Nancy (DCH)

Sent: Wednesday, September 30, 2015 5:22 PM

To: Miller, Corinne (DCH); Miller, Mark (DCH); LyonCallo, Sarah (DCH); Dykema, Linda D. (DCH); Priem, Wesley F. (DCH); Travis, Rashmi (DCH); Wells, Eden (DCH)

Subject: FW: Hurley -- follow up about the question on Hurley lab results

Hi all -- I talked to Bob to confirm the information I had shared about the Hurley lab results. It is a little more nuanced than I had explained, forwarding Bob's explanation, FYI.

From: Scott, Robert L. (DCH)

Sent: Wednesday, September 30, 2015 5:05 PM

To: Peeler, Nancy (DCH)

Subject: Hurley

Hurley Medical Center is listed as the "Provider" on approximately half of the blood lead results we received for Flint children in 2014—I assume that pattern holds in 2015 and in recent years. Warde Medical Lab is listed as the "Laboratory" on those results. Warde reported the results to CLPPP in accordance with State law.

I can't say whether the blood specimens were a) drawn at Hurley's lab, or b) simply passed through Hurley's lab—from physician office to Hurley to Warde for analysis. As I understand it, both scenarios are common at various hospital labs.

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Thursday, October 01, 2015 11:10 AM
To: MDHHS-IRB
Cc: Peeler, Nancy (DHHS)
Subject: RE: correspondence with Hurley

Ian, thanks so much for letting me know! I may have been reading too much into their brief silence.

From: MDHHS-IRB
Sent: Thursday, October 01, 2015 10:37 AM
To: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>
Subject: RE: correspondence with Hurley

Hi Bob,

I heard from Jenny LaChance a moment ago. We discussed the comments I had made on the proposal and the need for additional detail justifying why what is requested is the minimum necessary information, and approaches to respond with that clarification. She indicated the team at Hurley will work to prepare revised information and get a response back sometime in the next few days.

Regards,
 -Ian

From: Scott, Robert L. (DHHS)
Sent: Thursday, October 01, 2015 9:06 AM
To: MDHHS-IRB
Subject: correspondence with Hurley

Ian,

Just checking: I haven't heard back from Mona or Jenny (the Hurley researchers) since I passed on your comments (and some thoughts of my own) about their IRB application. Have you had any correspondence with them since about 1:00pm yesterday?

Thanks,
 Bob

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Thursday, October 01, 2015 3:07 PM
To: Peeler, Nancy (DHHS)
Subject: Hurley IRB revised

Nancy,

FYI, Hurley has sent revised documents for their IRB, and I've forwarded them to MDHHS IRB.

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Thursday, October 01, 2015 3:41 PM
To: Peeler, Nancy (DHHS)
Subject: RE: Hurley IRB revised

How about this? I'll check email tomorrow at 10:00, 12:00, 2:00 and 4:00 from home (not going anywhere). If I can handle it from home, I will; if not, I'll email you.

If the IRB is approved tomorrow, I can create their file on Monday. Am I correct that we still need a "go-ahead" from MDHHS Administration before sending the file?

From: Peeler, Nancy (DHHS)
Sent: Thursday, October 01, 2015 3:20 PM
To: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>
Subject: Re: Hurley IRB revised

:). I assume they'll go in today? If you are off tomorrow, can we make a plan for who will keep this moving tomorrow if needed? Prob need to give Hurley a contract person. I can do it via email from my meeting, or is there a better approach?

Sent from my iPhone

On Oct 1, 2015, at 3:07 PM, Scott, Robert L. (DHHS) <ScottR9@michigan.gov> wrote:

Nancy,

FYI, Hurley has sent revised documents for their IRB, and I've forwarded them to MDHHS IRB.

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Thursday, October 01, 2015 6:05 PM
To: Peeler, Nancy (DHHS)
Subject: FW: MDHHS IRB Approval - 201509-11-EA

FYI

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Thursday, October 01, 2015 5:52 PM
To: MDHHS-IRB <MDHHS-IRB@michigan.gov>
Cc: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>; Travis, Rashmi (DHHS) <TravisR@michigan.gov>
Subject: Re: MDHHS IRB Approval - 201509-11-EA

Thank you for the rapid approval.

Bob please let me know how I can get the data.

Mona Hanna-Attisha MD MPH FAAP
 Director, Pediatric Residency Program
 Hurley Children's Hospital
 Michigan State University

On Oct 1, 2015, at 5:48 PM, MDHHS-IRB <MDHHS-IRB@michigan.gov> wrote:

Please see the attached determination notice indicating MDHHS IRB approval of your research project for a period of 1 year. A hard copy of this notice will be provided to the Responsible MDHHS Employee. This IRB approval is for the study protocol, IRB application, and the most recent version of study documents in the form submitted to the IRB. Please see the comment section of the determination notice for specific requirements or additional details (if any) related to this approval. Any changes to the protocol or approved study documents must be reviewed and approved by the MDHHS IRB prior to implementation unless those changes are necessary to eliminate apparent immediate hazards to study subjects.

Any severe adverse events or unexpected problems involving risks to research subjects must be reported to the MDHHS IRB as soon as possible (usually within 48 hours of discovery).

Prior to the time this IRB approval expires, a report on the status of this research should be submitted to the MDHHS IRB to facilitate continued MDHHS IRB approval, or study closure.

Don't hesitate to contact the MDHHS IRB with any questions or concerns.

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

This message, including any attachments is intended solely for the use of the named recipient(s) and may contain confidential and/or privileged information. Any unauthorized review, use, disclosure, or distribution of any confidential and/or privileged information contained in this e-mail is expressly prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy any and all copies of the original message.

<20150911 11-IEA.pdf>

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Friday, October 02, 2015 10:27 AM
To: Mona Hanna-Attisha; MDHHS-IRB
Cc: Travis, Rashmi (DHHS); Peeler, Nancy (DHHS)
Subject: RE: MDHHS IRB Approval - 201509-11-EA

Mona,

I'm authorized to provide you with the file at 1:30 this afternoon. It can be delivered either of two ways:

- 1) I can post it to our secure FTP site on Michigan's Single Sign-On page. That's our usual method, but it would require a couple of minutes of your time to get signed up. I can send instructions in you wish.
- 2) I can send it by email as a zipped and encrypted attachment. You'd need WinZip and the password to unzip it. I could send the password to a fax number if you provide one.

Please let me know which you'd prefer.

A few words about the file:

It has 18,688 records, all blood lead results currently in our system for children less than five years of age at time of test, with address listed as Genesee County, with specimen date from 1/1/2013 to 9/15/2015.

The fields are Child ID (unique to each child), date of birth, specimen date, house number, street name, patient city, patient zip code, pb result, sample type (V-venous, C-capillary or blank-unknown), gender code (M, F, or blank), county, and serial number (a unique ID for each record).

The file format is tab-delimited text.

I think that's everything, but if you have questions after reviewing the file, please let me know.

Bob

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Thursday, October 01, 2015 5:52 PM
To: MDHHS-IRB <MDHHS-IRB@michigan.gov>
Cc: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>; Travis, Rashmi (DHHS) <TravisR@michigan.gov>
Subject: Re: MDHHS IRB Approval - 201509-11-EA

Thank you for the rapid approval.

Bob please let me know how I can get the data.

Mona Hanna-Attisha MD MPH FAAP
Director, Pediatric Residency Program
Hurley Children's Hospital
Michigan State University

On Oct 1, 2015, at 5:48 PM, MDHHS-IRB <MDHHS-IRB@michigan.gov> wrote:

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Don't hesitate to contact the MDHHS IRB with any questions or concerns.

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

This message, including any attachments is intended solely for the use of the named recipient(s) and may contain confidential and/or privileged information. Any unauthorized review, use, disclosure, or distribution of any confidential and/or privileged information contained in this e-mail is expressly prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy any and all copies of the original message.

<201509-11-EA.pdf>

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Friday, October 02, 2015 1:32 PM
To: Mona Hanna-Attisha; Jenny LaChance
Cc: Peeler, Nancy (DHHS); Travis, Rashmi (DHHS)
Subject: The requested file has been sent

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Friday, October 02, 2015 4:17 PM
To: Cooper, Jessica (DHHS); Peeler, Nancy (DHHS)
Subject: Re: File has been downloaded

Jessie, you rock! Many thanks!

From: Cooper, Jessica (DHHS)
Sent: Friday, October 2, 2015 4:05:19 PM
To: Peeler, Nancy (DHHS); Scott, Robert L. (DHHS)
Subject: File has been downloaded

Mona and Jenny are all set. I helped her get access and download the file.

She said Thank you so much😊

Jessica Cooper

Data Technician

CooperJ3@michigan.gov

Michigan Department of Health and Human Services

Childhood Lead Poisoning Prevention Program

PO Box 30195

4th Floor

Lansing MI 48909

Phone: (517) 335-8912

Fax: (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Friday, October 02, 2015 6:43 PM
To: LyonCallo, Sarah (DHHS); Mona Hanna-Attisha; Peeler, Nancy (DHHS); Jenny LaChance; Miller, Corinne (DHHS); McKane, Patricia (DHHS)
Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: Re: The requested file has been sent.

We round up from .5 and round down from .4

From: LyonCallo, Sarah (DHHS)
Sent: Friday, October 2, 2015 6:33:14 PM
To: Mona Hanna-Attisha; Peeler, Nancy (DHHS); Scott, Robert L. (DHHS); Jenny LaChance; Miller, Corinne (DHHS); McKane, Patricia (DHHS)
Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: RE: The requested file has been sent

You are correct that lead level results in the file you received are rounded (i.e., no decimal places). The data set we are using in epidemiology (which is the same type of file Mr. Scott would have pulled from the data warehouse for you) contains values from 1 to 49. Are you seeing the 10 and above levels?

I do not know the rounding rules for the lead result data and am still working on getting you that information.

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Friday, October 02, 2015 5:25 PM
To: Peeler, Nancy (DHHS); Scott, Robert L. (DHHS); Jenny LaChance; Miller, Corinne (DHHS); LyonCallo, Sarah (DHHS); McKane, Patricia (DHHS)
Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: RE: The requested file has been sent

Quick question:

We have the data and are starting to geocode it!

All of your lead level results are single numbers with no decimals?? It's kinda weird. All of our lab data included decimals and there was also kids with <0.5 levels (undetectable).

Does your lead data just not have decimals? Do numbers get round up or round down?

Thanks! Mona

(I do understand that it's Friday. Sorry.)

Mona Hanna-Attisha MD MPH FAAP
 Program Director Pediatric Residency
 Hurley Children's Hospital at Hurley Medical Center
 Michigan State University College of Human Medicine
 Department of Pediatrics and Human Development
Mhanna1@hurleymc.com

HURLEY CHILDREN'S HOSPITAL

From: Peeler, Nancy (DHHS) [<mailto:PeelerN@michigan.gov>]
Sent: Friday, October 02, 2015 3:07 PM
To: Mona Hanna-Attisha; Scott, Robert L. (DHHS); Jenny LaChance
Cc: Travis, Rashmi (DHHS)
Subject: RE: The requested file has been sent
Importance: High

Good afternoon, Mona -

Today is Bob's scheduled day off. He came in to prepare and send the file, but has left for the rest of the day. I will see if I can reach him to find out what step to take to get you access to the data.

Can you give me any more detail that I can share with him, if I can reach him? It sounds like you did receive the email with the file attached, and the password (I assume via fax). If those two pieces are in place, is the issue that it won't 'unzip'?

Nancy Peeler, Manager
 Early Childhood Health Section

From: Mona Hanna-Attisha [<mailto:MHanna1@hurleymc.com>]
Sent: Friday, October 02, 2015 2:59 PM
To: Scott, Robert L. (DHHS); Jenny LaChance
Cc: Peeler, Nancy (DHHS); Travis, Rashmi (DHHS)
Subject: RE: The requested file has been sent

We are unable to open the file that you sent. Can you try to send again or let us know how to open it another way. Thanks! We were really hoping to review today. thanks!

From: Scott, Robert L. (DHHS) [<mailto:ScottR9@michigan.gov>]
Sent: Friday, October 02, 2015 1:32 PM
To: Mona Hanna-Attisha; Jenny LaChance
Cc: Peeler, Nancy (DHHS); Travis, Rashmi (DHHS)
Subject: The requested file has been sent

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Friday, October 02, 2015 7:36 PM
To: Mona Hanna-Attisha; Peeler, Nancy (DHHS); Jenny LaChance; Miller, Corinne (DHHS); LyonCallo, Sarah (DHHS); McKane, Patricia (DHHS)
Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: Re: The requested file has been sent

Mona,

The integers in your file are the values we have stored in our blood lead surveillance system; that's our current protocol.

To my knowledge, the CDC's Lead program has not taken a stance on whether to store decimals or not.

Bob

From: Mona Hanna-Attisha <MHanna1@hurleymc.com>
Sent: Friday, October 2, 2015 5:24 PM
To: Peeler, Nancy (DHHS); Scott, Robert L. (DHHS); Jenny LaChance; Miller, Corinne (DHHS); LyonCallo, Sarah (DHHS); McKane, Patricia (DHHS)
Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: RE: The requested file has been sent

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Does your lead data just not have decimals? Do numbers get round up or round down?

Thanks! Mona

(I do understand that it's Friday. Sorry.)

Mona Hanna-Attisha MD MPH FAAP
 Program Director Pediatric Residency
 Hurley Children's Hospital at Hurley Medical Center
 Michigan State University College of Human Medicine
 Department of Pediatrics and Human Development
 Mhanna1@hurleymc.com



From: Peeler, Nancy (DHHS) [mailto:PeelerN@michigan.gov]
Sent: Friday, October 02, 2015 3:07 PM
To: Mona Hanna-Attisha; Scott, Robert L. (DHHS); Jenny LaChance
Cc: Travis, Rashmi (DHHS)
Subject: RE: The requested file has been sent
Importance: High

Good afternoon, Mona -

Today is Bob's scheduled day off. He came in to prepare and send the file, but has left for the rest of the day. I will see if I can reach him to find out what step to take to get you access to the data.

Can you give me any more detail that I can share with him, if I can reach him? It sounds like you did receive the email with the file attached, and the password (I assume via fax). If those two pieces are in place, is the issue that it won't 'unzip'?

Nancy Peeler, Manager
 Early Childhood Health Section

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Friday, October 02, 2015 2:59 PM
To: Scott, Robert L. (DHHS); Jenny LaChance
Cc: Peeler, Nancy (DHHS); Travis, Rashmi (DHHS)
Subject: RE: The requested file has been sent

We are unable to open the file that you sent. Can you try to send again or let us know how to open it another way. Thanks! We were really hoping to review today. thanks!

From: Scott, Robert L. (DHHS) [mailto:ScottR9@michigan.gov]
Sent: Friday, October 02, 2015 1:32 PM
To: Mona Hanna-Attisha; Jenny LaChance
Cc: Peeler, Nancy (DHHS); Travis, Rashmi (DHHS)
Subject: The requested file has been sent

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DHHS)
Sent: Saturday, October 03, 2015 3:02 PM
To: Travis, Rashmi (DHHS); Peeler, Nancy (DHHS)
Subject: Re: anyone have nancy P or Bob S cell phone numbers?
Attachments: Lead results are squishy.docx

Nancy and Rashmi,

Please see attached. This is what I'd like to send Mona, but please feel free to tell me why I shouldn't. ☺

I do think that every researcher asking for lead data should get some version of this information; I'm feeling like I should have been doing so in years past.

As Nancy said to me yesterday, we should all get together and talk about how BLLs are currently stored, and what changes should be made going forward. Mark Knottnerus and Tom Mailand from the MDHHS Trace Metals Lab should be included in the discussion. That discussion (or maybe a separate one), should also cover the difference between capillary and venous, the large number of unconfirmed capillary tests, and how best to represent them in data reports.

(My personal cell number is PPI Please feel free to call.)

Thanks,
 Bob

From: Travis, Rashmi (DHHS)
Sent: Saturday, October 3, 2015 3:51 AM
To: Scott, Robert L. (DHHS)
Cc: Peeler, Nancy (DHHS)
Subject: Fwd: anyone have nancy P or Bob S cell phone numbers?

Bob
 Please see chain of emails below on why rounding up is done in this way?
 Thanks
 Rashmi

Sent from my iPhone

Begin forwarded message:

From: "Wells, Eden (DHHS)" <WellsE3@michigan.gov>
Date: October 2, 2015 at 7:19:50 PM EDT
To: "LyonCallo, Sarah (DHHS)" <lyoncallos@michigan.gov>
Cc: "Travis, Rashmi (DHHS)" <TravisR@michigan.gov>, "Miller, Corinne (DHHS)"

<MillerC39@michigan.gov>

Subject: Re: anyone have nancy P or Bob S cell phone numbers?

So I can take a deep breath now? I nearly keeled over...Rashmi- he may want to explain that to her if rounding is CDC protocol if that is tuneup, because she needs confidence in our processes.

Sent from my iPhone

On Oct 2, 2015, at 7:17 PM, LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov> wrote:

My understanding is this is CDC protocol for handling the clinical data to get it into surveillance format. What Bob sends is the same data that goes to local health and to CDC (used to be STELLAR) – it is the raw surveillance data. I don't know the protocols for how the clinical tests come in through the warehouse –this is really a Bob question.

From: Wells, Eden (DHHS)

Sent: Friday, October 02, 2015 7:11 PM

To: LyonCallo, Sarah (DHHS)

Cc: Travis, Rashmi (DHHS); Miller, Corinne (DHHS)

Subject: Re: anyone have nancy P or Bob S cell phone numbers?

I sent an email that is portraying a real concern--- Sarah would having tenths have helped the sensitivity of our data??????

Sent from my iPhone

On Oct 2, 2015, at 7:06 PM, LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov> wrote:

Bob has already responded and Mona has come back with more questions. Someone needs to be responsive over the weekend or to say when we would be able to answer, I think – as Mona's group works with the data, there will be more questions.

From: Travis, Rashmi (DHHS)

Sent: Friday, October 02, 2015 7:05 PM

To: Wells, Eden (DHHS)

Cc: LyonCallo, Sarah (DHHS); Miller, Corinne (DHHS)

Subject: Re: anyone have nancy P or Bob S cell phone numbers?

I emailed Bob and Nancy. Nancy may check her email over weekend. Is there an urgent need to contact on the weekend?

Sent from my iPhone

On Oct 2, 2015, at 6:56 PM, Wells, Eden (DHHS)

<WellsE3@michigan.gov> wrote:

Ugh

Sent from my iPhone

On Oct 2, 2015, at 6:38 PM, LyonCallo, Sarah (DHHS)
<lyoncallos@michigan.gov> wrote:

It would be great if Bob or Nancy could be contacted because I cannot find the answer to Mona's question about rounding in any materials on CDC or MDHHS CLPP materials.... Specifically Mona wants to know how a lab test with decimal values is rounded in the data base.

Do we round up?

Do we round down?

Do we use the rounding rule?

I am assuming we are following a cdc protocol on rounding rules, but can't find any mention of rounding in the data specs I have been able to find thus far.....

Lead results are squishy.

In Michigan:

- Any specimen that could not be analyzed (clotted, insufficient amount, etc.) is not included here.
- Any result of "below detection limit" or similar text is stored as a 1.
- Any result of less than 1 (0.0, 0.2, 0.5, 0.8, etc.) is stored as a 1.
- Any numerical result in decimals (above 1) is rounded to the nearest integer (rounding up at .5).
- Any result reported as <X is stored as the next lowest integer—e.g., <4 is stored as 3.

Everywhere:

- Different labs using different methods of analysis have different detection limits.
- Different methods of analysis have different levels of precision.
- LeadCare analyzers (including LeadCare II) have a detection limit of 3.3. LeadCare results now account for nearly half? A third? Of all results statewide.
- Regardless of the method of analysis, the method of blood draw can be either venous or capillary. Capillary is considered a screening test, and any elevated capillary test should be confirmed with a venous test. In many cases, though, the venous test never occurs—either one or more repeat capillary tests are done, or the child never gets a second test of either type.
- This situation has been further confused since 2012, when the reference level went from 10 to 5. Even more capillary BLLs 5-9 go unconfirmed than those ≥ 10 .
- THE REFERENCE LEVEL FOR BLOOD LEAD IS "5" NOT "5.0."

Peeler, Nancy (DHHS)

From: Wells, Eden (DHHS)
Sent: Friday, October 02, 2015 7:42 PM
To: Scott, Robert L. (DHHS); Peeler, Nancy (DHHS); LyonCallo, Sarah (DHHS); Travis, Rashmi (DHHS); Miller, Corinne (DHHS)
Subject: Fwd: The requested file has been sent

You are a true rock star, Bob--- sorry for doing a little freak out- I am going to tape my fingers so I can't type emails anymore as my small brain is now rattling around.

I owe you all- and CHOCOLATE is due!

Sent from my iPhone

Begin forwarded message:

From: "Scott, Robert L. (DHHS)" <ScottR9@michigan.gov>
Date: October 2, 2015 at 7:36:19 PM EDT
To: Mona Hanna-Attisha <MHanna1@hurleymc.com>, "Peeler, Nancy (DHHS)" <PeelerN@michigan.gov>, Jenny LaChance <JLachan1@hurleymc.com>, "Miller, Corinne (DHHS)" <MillerC39@michigan.gov>, "LyonCallo, Sarah (DHHS)" <lyoncallos@michigan.gov>, "McKane, Patricia (DHHS)" <McKaneP@michigan.gov>
Cc: "Travis, Rashmi (DHHS)" <TravisR@michigan.gov>, "Wells, Eden (DHHS)" <WellsE3@michigan.gov>
Subject: Re: The requested file has been sent

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Sent: Friday, October 2, 2015 5:24 PM
To: Peeler, Nancy (DHHS); Scott, Robert L. (DHHS); Jenny LaChance; Miller, Corinne (DHHS); LyonCallo,

Sarah (DHHS); McKane, Patricia (DHHS)
Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: RE: The requested file has been sent

Quick question:

We have the data and are starting to geocode it!

All of your lead level results are single numbers with no decimals?? It's kinda weird. All of our lab data included decimals and there was also kids with <0.5 levels (undetectable).

Does your lead data just not have decimals? Do numbers get round up or round down?

Thanks! Mona

(I do understand that it's Friday. Sorry.)

Mona Hanna-Attisha MD MPH FAAP
 Program Director Pediatric Residency
 Hurley Children's Hospital at Hurley Medical Center
 Michigan State University College of Human Medicine
 Department of Pediatrics and Human Development
Mhanna1@hurleymc.com

From: Peeler, Nancy (DHHS) [<mailto:PeelerN@michigan.gov>]
Sent: Friday, October 02, 2015 3:07 PM
To: Mona Hanna-Attisha; Scott, Robert L. (DHHS); Jenny LaChance
Cc: Travis, Rashmi (DHHS)
Subject: RE: The requested file has been sent
Importance: High

Good afternoon, Mona -

Today is Bob's scheduled day off. He came in to prepare and send the file, but has left for the rest of the day. I will see if I can reach him to find out what step to take to get you access to the data.

Can you give me any more detail that I can share with him, if I can reach him? It sounds like you did receive the email with the file attached, and the password (I assume via fax). If those two pieces are in place, is the issue that it won't 'unzip'?

Nancy Peeler, Manager
 Early Childhood Health Section

From: Mona Hanna-Attisha [<mailto:Mhanna1@hurleymc.com>]
Sent: Friday, October 02, 2015 2:59 PM
To: Scott, Robert L. (DHHS); Jenny LaChance
Cc: Peeler, Nancy (DHHS); Travis, Rashmi (DHHS)
Subject: RE: The requested file has been sent

We are unable to open the file that you sent. Can you try to send again or let us know how to open it another way. Thanks! We were really hoping to review today. thanks!

From: Scott, Robert L. (DHHS) [<mailto:ScottR9@michigan.gov>]
Sent: Friday, October 02, 2015 1:32 PM
To: Mona Hanna-Attisha; Jenny LaChance
Cc: Peeler, Nancy (DHHS); Travis, Rashmi (DHHS)
Subject: The requested file has been sent

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Wells, Eden (DHHS)
Sent: Friday, October 02, 2015 7:27 PM
To: Scott, Robert L. (DHHS); Peeler, Nancy (DHHS); Travis, Rashmi (DHHS); Miller, Corinne (DHHS); LyonCallo, Sarah (DHHS)
Subject: Fwd: The requested file has been sent

Whew... Have a good weekend all!

Sent from my iPhone

Begin forwarded message:

From: Mona Hanna-Attisha <MHanna1@hurleymc.com>
Date: October 2, 2015 at 7:23:14 PM EDT
To: "Wells, Eden (DHHS)" <WellsE3@michigan.gov>
Subject: Re: The requested file has been sent

It's ok, Eden. We can wait until Monday to get more info/clarification. Thanks so much for everything.

Mona Hanna-Attisha MD MPH FAAP
 Director, Pediatric Residency Program
 Hurley Children's Hospital
 Michigan State University

On Oct 2, 2015, at 7:16 PM, Wells, Eden (DHHS) <WellsE3@michigan.gov> wrote:

Hi Monal Glad Bob got back to you- question: are you planning to work on this all weekend- if so I will advise Bob and Nancy

Sent from my iPhone

On Oct 2, 2015, at 6:45 PM, Mona Hanna-Attisha <MHanna1@hurleymc.com> wrote:

Is there a way to get the original non-rounded numbers?

Mona Hanna-Attisha MD MPH FAAP
 Director, Pediatric Residency Program
 Hurley Children's Hospital
 Michigan State University

On Oct 2, 2015, at 6:43 PM, Scott, Robert L. (DHHS) <ScottR9@michigan.gov> wrote:

We round up from .5 and round down from .4

From: LyonCallo, Sarah (DHHS)
Sent: Friday, October 2, 2015 6:33:14 PM

To: Mona Hanna-Attisha; Peeler, Nancy (DHHS); Scott, Robert L. (DHHS); Jenny LaChance; Miller, Corinne (DHHS); McKane, Patricia (DHHS)
Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: RE: The requested file has been sent

You are correct that lead level results in the file you received are rounded (i.e., no decimal places). The data set we are using in epidemiology (which is the same type of file Mr. Scott would have pulled from the data warehouse for you) contains values from 1 to 49. Are you seeing the 10 and above levels?

I do not know the rounding rules for the lead result data and am still working on getting you that information.

From: Mona Hanna-Attisha
[\[mailto:MHanna1@hurleymc.com\]](mailto:MHanna1@hurleymc.com)
Sent: Friday, October 02, 2015 5:25 PM
To: Peeler, Nancy (DHHS); Scott, Robert L. (DHHS); Jenny LaChance; Miller, Corinne (DHHS); LyonCallo, Sarah (DHHS); McKane, Patricia (DHHS)
Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: RE: The requested file has been sent

Quick question:

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 Program Director Pediatric Residency
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 Michigan State University College of Human Medicine
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Mhanna1@hurleymc.com

<image001.jpg>

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To: Mona Hanna-Attisha; Scott, Robert L. (DHHS);
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Nancy Peeler, Manager
 Early Childhood Health Section

From: Mona Hanna-Attisha
[\[mailto:MHanna1@hurleymc.com\]](mailto:MHanna1@hurleymc.com)
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Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

image001.jpg

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Cc: Travis, Rashmi (DHHS); Wells, Eden (DHHS)
Subject: RE: The requested file has been sent

Dr. Hanna-Attisha,
 I got your email and am working on an answer for you.
 Sarah

Sarah Lyon-Callo, MA, MS
 Director, Lifecourse Epidemiology and Genomics Division
 Bureau of Disease Control, Prevention and Epidemiology
 Population Health and Community Services Administration
 Michigan Department of Health and Human Services
 201 Townsend St., 4th Floor Capitol View Building
 PO Box 30195
 Lansing, MI 48909
 PH: 517-335-9315

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Subject: The requested file has been sent

Robert L. Scott

Childhood Lead Poisoning Prevention Program

Michigan Department of Health & Human Services

(517) 335-8178

fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Peeler, Nancy (DHHS)
Sent: Friday, October 02, 2015 3:47 PM
To: Mona Hanna-Attisha
Subject: RE: The requested file has been sent

I understand that Bob is putting you in touch with our program staff person, Jessica Cooper, to set up the SSO page.

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Friday, October 02, 2015 3:23 PM
To: Peeler, Nancy (DHHS)
Subject: RE: The requested file has been sent

Sorry to have to bother him. Maybe we can try the Michigan's Single Sign-On page way.

From: Peeler, Nancy (DHHS) [mailto:PeelerN@michigan.gov]
Sent: Friday, October 02, 2015 3:22 PM
To: Mona Hanna-Attisha; Scott, Robert L. (DHHS); Jenny LaChance
Cc: Travis, Rashmi (DHHS)
Subject: RE: The requested file has been sent

I left a message for Bob, in the event that he might be able to shed more light on this.

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Friday, October 02, 2015 3:16 PM
To: Peeler, Nancy (DHHS); Scott, Robert L. (DHHS); Jenny LaChance
Cc: Travis, Rashmi (DHHS)
Subject: RE: The requested file has been sent

Yes, we got the fax, but the attachment was the below:

McAfee®

Protected Archive Detected

A password-protected file could not be scanned.

See your system administrator for further information.

Copyright © 1993-2015 McAfee, Inc.
 All Rights Reserved.
<http://www.mcafee.com>

From: Peeler, Nancy (DHHS) [mailto:PeelerN@michigan.gov]
Sent: Friday, October 02, 2015 3:07 PM
To: Mona Hanna-Attisha; Scott, Robert L. (DHHS); Jenny LaChance
Cc: Travis, Rashmi (DHHS)

Subject: RE: The requested file has been sent
Importance: High

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Early Childhood Health Section

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Subject: The requested file has been sent

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Peeler, Nancy (DHHS)

From: Mona Hanna-Attisha <MHanna1@hurleymc.com>
Sent: Friday, October 02, 2015 10:48 AM
To: Scott, Robert L. (DHHS); MDHHS-IRB; Jenny LaChance
Cc: Travis, Rashmi (DHHS); Peeler, Nancy (DHHS)
Subject: RE: MDHHS IRB Approval - 201509-11-EA

Thanks Bob. We will go with option 2.

The fax number here is 810-262-9736. Please include attn to me.

Much appreciated! Mona

From: Scott, Robert L. (DHHS) [mailto:ScottR9@michigan.gov]
Sent: Friday, October 02, 2015 10:27 AM
To: Mona Hanna-Attisha; MDHHS-IRB
Cc: Travis, Rashmi (DHHS); Peeler, Nancy (DHHS)
Subject: RE: MDHHS IRB Approval - 201509-11-EA

Mona,

I'm authorized to provide you with the file at 1:30 this afternoon. It can be delivered either of two ways:

- 1) I can post it to our secure FTP site on Michigan's Single Sign-On page. That's our usual method, but it would require a couple of minutes of your time to get signed up. I can send instructions in you wish.
- 2) I can send it by email as a zipped and encrypted attachment. You'd need WinZip and the password to unzip it. I could send the password to a fax number if you provide one.

Please let me know which you'd prefer.

A few words about the file:

It has 18,688 records, all blood lead results currently in our system for children less than five years of age at time of test, with address listed as Genesee County, with specimen date from 1/1/2013 to 9/15/2015.

The fields are Child ID (unique to each child), date of birth, specimen date, house number, street name, patient city, patient zip code, pb result, sample type (V-venous, C-capillary or blank-unknown), gender code (M, F, or blank), county, and serial number (a unique ID for each record).

The file format is tab-delimited text.

I think that's everything, but if you have questions after reviewing the file, please let me know.

Bob

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Thursday, October 01, 2015 5:52 PM
To: MDHHS-IRB <MDHHS-IRB@michigan.gov>
Cc: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>; Travis, Rashmi (DHHS) <TravisR@michigan.gov>
Subject: Re: MDHHS IRB Approval - 201509-11-EA

Thank you for the rapid approval.

Bob please let me know how I can get the data.

Mona Hanna-Attisha MD MPH FAAP
Director, Pediatric Residency Program
Hurley Children's Hospital
Michigan State University

On Oct 1, 2015, at 5:48 PM, MDHHS-IRB <MDHHS-IRB@michigan.gov> wrote:

Please see the attached determination notice indicating MDHHS IRB approval of your research project for a period of 1 year. A hard copy of this notice will be provided to the Responsible MDHHS Employee. This IRB approval is for the study protocol, IRB application, and the most recent version of study documents in the form submitted to the IRB. Please see the comment section of the determination notice for specific requirements or additional details (if any) related to this approval. Any changes to the protocol or approved study documents must be reviewed and approved by the MDHHS IRB prior to implementation unless those changes are necessary to eliminate apparent immediate hazards to study subjects.

Any severe adverse events or unexpected problems involving risks to research subjects must be reported to the MDHHS IRB as soon as possible (usually within 48 hours of discovery).

Prior to the time this IRB approval expires, a report on the status of this research should be submitted to the MDHHS IRB to facilitate continued MDHHS IRB approval, or study closure.

Don't hesitate to contact the MDHHS IRB with any questions or concerns.

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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<201509-11-EA.pdf>

Peeler, Nancy (DHHS)

From: Wells, Eden (DHHS)
Sent: Friday, October 02, 2015 10:01 AM
To: Travis, Rashmi (DHHS)
Cc: Peeler, Nancy (DHHS); Fink, Brenda (DHHS); Colston, Leslie (DHHS)
Subject: RE: TIME SENSITIVE:: MDHHS IRB Approval - 201509-11-EA

Good to go at 1:30

From: Travis, Rashmi (DHHS)
Sent: Friday, October 02, 2015 6:31 AM
To: Wells, Eden (DHHS)
Cc: Peeler, Nancy (DHHS); Fink, Brenda (DHHS); Colston, Leslie (DHHS)
Subject: Re: TIME SENSITIVE:: MDHHS IRB Approval - 201509-11-EA

Eden

Ok we will wait. Please let us know status after the press conference in ok to share data.

Thanks

Rashmi

Sent from my iPhone

On Oct 1, 2015, at 8:20 PM, Wells, Eden (DHHS) <WellsE3@michigan.gov> wrote:

Governor's Communication Plan states data not to be shared with HURLEY/LHD until I call her/them before 1:30 press conference(about 1 PM) Once Press conference starts at 1:30, that would be fine, I would think!!!!

From: Peeler, Nancy (DHHS)
Sent: Thursday, October 1, 2015 6:20 PM
To: Wells, Eden (DHHS)
Cc: Travis, Rashmi (DHHS); Fink, Brenda (DHHS); Colston, Leslie (DHHS)
Subject: FW: MDHHS IRB Approval - 201509-11-EA

Hi – the IRB approval for Hurley came through late today (5:48pm), and they are asking for the data file (5:52pm).

Dr. Wells, you asked us to coordinate with you on this request, look forward to hearing back from you about next steps.

Nancy

From: Scott, Robert L. (DHHS)
Sent: Thursday, October 01, 2015 6:05 PM
To: Peeler, Nancy (DHHS)
Subject: FW: MDHHS IRB Approval - 201509-11-EA

FYI

From: Mona Hanna-Attisha [<mailto:MHanna1@hurleymc.com>]
Sent: Thursday, October 01, 2015 5:52 PM
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Cc: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>; Travis, Rashmi (DHHS) <TravisR@michigan.gov>
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<201509-11-EA.pdf>

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To: Peeler, Nancy (DHHS)
Cc: Fink, Brenda (DHHS); Colston, Leslie (DHHS)
Subject: Re: MDHHS IRB Approval - 201509-11-EA

Nancy

Please let Corinne and staff know with a cc to me. Sounds like we are in s holding pattern as per instructions with Gov office. Let Corrine know that too. I will let you know when we hear further action from Eden.

Thanks

Rashmi

Sent from my iPhone

On Oct 1, 2015, at 6:37 PM, Peeler, Nancy (DHHS) <PeelerN@michigan.gov> wrote:

Rashmi, do you want me to check with Corinne and 'all' – or is that something you want to do?

We were asked to coordinate with Dr. Wells, Geralyn Lasher and Angela Minicuci were also on the phone at that time, and Dr. Wells is now including Corinne and I assume her Epi partners.

From: Wells, Eden (DHHS)
Sent: Thursday, October 01, 2015 6:34 PM
To: Peeler, Nancy (DHHS)
Cc: Travis, Rashmi (DHHS); Fink, Brenda (DHHS); Colston, Leslie (DHHS)
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Share tomorrow if ok by with all including Corinne

Sent from my iPhone

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~~20150911-1-EA.pdf~~

Peeler, Nancy (DHHS)

From: Wells, Eden (DCH)
Sent: Tuesday, September 29, 2015 6:16 PM
To: Peeler, Nancy (DCH)
Subject: Re: TIME SENSITIVE: Fw: Discrepancies

Sorry, just realized I had only replied to you, so looped all in on my response later...If Geralyn wants, I have no quibble! And really, thank you!!

From: Peeler, Nancy (DCH)
Sent: Tuesday, September 29, 2015 6:01 PM
To: Wells, Eden (DCH)
Subject: RE: TIME SENSITIVE: Fw: Discrepancies

Many cooks in the kitchen, all doing their best. So should we respond to Geralyn's request?

From: Wells, Eden (DCH)
Sent: Tuesday, September 29, 2015 6:00 PM
To: Peeler, Nancy (DCH)
Subject: Re: TIME SENSITIVE: Fw: Discrepancies

Sorry, that was my bad...which is one of the problems---lots of people doing different analyses.

Thanks for the info, I will forward to her!

Eden

From: Peeler, Nancy (DCH)
Sent: Tuesday, September 29, 2015 3:53 PM
To: Wells, Eden (DCH)
Cc: Miller, Corinne (DCH); Lasher, Geralyn (DCH); Hertel, Elizabeth (DCH); Scott, Robert L. (DCH)
Subject: RE: TIME SENSITIVE: Fw: Discrepancies

Bob went back and looked at his numbers.

For the first chart, with the elevated blood lead levels, he found one number in the 2014-2015 row that changed, and he confirmed that the data in the later version was correct (the version dated September 23).

In the second chart, showing testing numbers, use the one dated September 23rd. That chart shows unduplicated tests (e.g. one test per child, per month), whereas the previous version did count some 'duplicate' tests.

I have copied Bob on this email, in case you have further questions.

I'd also like to ask for clarification on one of Geralyn's earlier emails today; Bob (CLPPP) had produced these descriptive charts – but it looked like Dr. Wells is asking Corinne to do that instead of CLPPP (it was a request to re-do the chart with

only younger children included). Trying not to duplicate efforts, so please clarify if you would like us to do that, or someone else. Thanks!

Nancy

From: Wells, Eden (DCH)
Sent: Tuesday, September 29, 2015 3:11 PM
To: Peeler, Nancy (DCH)
Cc: Miller, Corinne (DCH); Lasher, Geralyn (DCH); Hertel, Elizabeth (DCH)
Subject: Re: TIME SENSITIVE: Fw: Discrepancies

fantastic, thanks!!

From: Peeler, Nancy (DCH)
Sent: Tuesday, September 29, 2015 3:04 PM
To: Wells, Eden (DCH)
Cc: Miller, Corinne (DCH); Lasher, Geralyn (DCH); Hertel, Elizabeth (DCH)
Subject: Re: TIME SENSITIVE: Fw: Discrepancies

I'll connect with him shortly, and we'll get back to you.

Sent from my iPad

On Sep 29, 2015, at 2:41 PM, Wells, Eden (DCH) <WellsE3@michigan.gov> wrote:

Hi Nancy,

I do not have Bob's email, so if you can talk to him; however, I got a request from Dr. Hanna-Attisha at Hurley today as to why the 2014-2015 may differ in the 2 pdf's she attached (received 9/15 and 9/25). FYI, she stated that Bob is great to work with.

However, due to different numbers and analyses and such flying around in the last 24 hours, please respond back to me ASAP regarding the discrepancies, and I can relay to her.

Thank you!

Eden

Eden V. Wells, MD, MPH, FACPM
 Chief Medical Executive
 Michigan Department of Health and Human Services
 201 Townsend Street, 5th Floor CVB
 Lansing, MI 48913
 Phone: 517-335-8011
wellse3@michigan.gov

From: Mona Hanna-Attisha <MHanna1@hurleymc.com>
Sent: Tuesday, September 29, 2015 1:07 PM

To: Wells, Eden (DCH)

Subject: FW: Discrepancies

Dr Wells, in regards to the discrepancy noted in state data. Attached are two PDF files that were sent regarding the state lead numbers.

The original PDF was sent on 9/15/15 to Dr Reynolds from Bob Scott from MDHHS's Childhood Lead Poisoning Prevention Program and the updated PDF was sent to me from Bob Scott last Friday.

The attached excel database (that I created) has two tabs that include the original and updated numbers. Yellow highlights are all the numbers that changed. It is very strange how many of the numbers have changed. I'm not sure if the updated numbers tried to refine the location to Flint proper???

The analyses of the data does not change very much (when you look at total annual EBL%) - there has been a statistically significant increase in EBL% since water change (2014-2015) where every year prior there has been a decrease (as has happened nationally). And this does not even include the fact that the data is not scientific - wrong age range and missing lots of EBLs by using first time lead analysis rather than highest lead.

Just thought the discrepancy was odd.

Mona Hanna-Attisha MD MPH FAAP

Program Director Pediatric Residency

Hurley Children's Hospital at Hurley Medical Center

Michigan State University College of Human Medicine

Department of Pediatrics and Human Development

Mhanna1@hurleymc.com

<Flint Testing and EBLs_updated 092315_with notes (2).pdf>

<Flint Testing and EBLs (4).pdf>

<STATELEADDATA with original and updated numbers.xlsx>

Peeler, Nancy (DHHS)

From: Mona Hanna-Attisha <MHanna1@hurleymc.com>
Sent: Wednesday, September 23, 2015 10:58 AM
To: Scott, Robert L. (DCH)
Cc: Lawrence Reynolds; Peeler, Nancy (DCH)
Subject: RE: IRBNet Board Action

Thank you. Greatly appreciated!

From: Scott, Robert L. (DCH) [ScottR9@michigan.gov]
Sent: Wednesday, September 23, 2015 10:56 AM
To: Mona Hanna-Attisha
Cc: Lawrence Reynolds; Peeler, Nancy (DCH)
Subject: RE: IRBNet Board Action

I will ASAP, but still trying to get caught up after being away.

-----Original Message-----

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Wednesday, September 23, 2015 10:55 AM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Lawrence Reynolds <lrey52@gmail.com>; Peeler, Nancy (DCH) <PeelerN@michigan.gov>
Subject: RE: IRBNet Board Action

Thanks. Will do today.

Are you able to look at EBL % as was previously done for the more recent months and for kids less than 5yr?

Mona Hanna-Attisha MD MPH

Director, Pediatric Residency Program

Hurley Children's Hospital at Hurley Medical Center

Assistant Professor, Department of Pediatrics and Human Development

Michigan State University College of Human Medicine

Office: 810-262-7257

mhanna1@hurleymc.com

From: Scott, Robert L. (DCH) [ScottR9@michigan.gov]

Sent: Wednesday, September 23, 2015 10:53 AM
 To: Mona Hanna-Attisha
 Cc: Lawrence Reynolds; Peeler, Nancy (DCH)
 Subject: RE: IRBNet Board Action

Mona,

I'll be happy to help with this. We'll need you to submit a DCH-1294 Data Use Agreement (attached) and an IRB Initial Review Application - Abbreviated for review by the MDHHS IRB. The latter is available at Michigan.gov/irb under "Information for New Applications." (The "Abbreviated" application is used whenever another IRB has already approved the project.) Please complete each of the two documents as far as you can, and send to me unsigned, as Word documents. I'll fill in the rest, and will send the DUA to our Legal department and the IRB app to our IRB contact. I'll ask each of them for as quick a review as possible.

Please let me know if you have questions.

Bob

Robert L. Scott
 Childhood Lead Poisoning Prevention Program Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

-----Original Message-----

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
 Sent: Wednesday, September 16, 2015 3:10 PM
 To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
 Cc: Lawrence Reynolds <lrey52@gmail.com>
 Subject: FW: IRBNet Board Action

Bob, I just received IRB approval to look at the City of Flint blood lead levels. I would love to get the raw data if that is possible. Attached is my study proposal and the IRB approval.

Specific fields that we are looking for include:

MCIR ID or some sort of identifier to ensure first time lead level only Zip code Date of Birth Date of Blood lead level Lead level

Would greatly appreciate your assistance! Thanks!

Mona Hanna-Attisha MD MPH FAAP
 Program Director Pediatric Residency
 Hurley Children's Hospital at Hurley Medical Center Michigan State University College of Human Medicine Department of Pediatrics and Human Development Mhanna1@hurleymc.com

-----Original Message-----

From: Nicolas Lecea [mailto:no-reply@irbnet.org]
Sent: Wednesday, September 16, 2015 2:09 PM
To: Jenny LaChance; Mona Hanna-Attisha
Subject: IRBNet Board Action

Please note that Hurley Medical Center Institutional Review Board has taken the following action on IRBNet:

Project Title: [807433-1] Analysis of Pediatric Blood Lead Levels Principal Investigator: Mona Hanna-Attisha, MD MPH

Submission Type: New Project
Date Submitted: September 15, 2015

Action: APPROVED
Effective Date: September 16, 2015
Review Type: Expedited Review

Should you have any questions you may contact Nicolas Lecea at nlecea1@hurleymc.com.

Thank you,
The IRBNet Support Team

www.irbnet.org

Peeler, Nancy (DHHS)

From: Mona Hanna-Attisha <MHanna1@hurleymc.com>
Sent: Tuesday, September 22, 2015 10:12 PM
To: Scott, Robert L. (DCH); Lawrence Reynolds; Laura Carravallah; Dr. Lawrence Reynolds, M.D.; MVALACAK@gchd.us; Hallwood, Dawn; Henry, James; Jenny LaChance; Holtrop, Teresa
Cc: Peeler, Nancy (DCH); Lishinski, Karen (DCH); Emily Houk (emily@r2pconsultants.com)
Subject: RE: Lead level data
Attachments: Pediatric Lead Exposure Flint Water.pdf

Bob,

I hope you are well and back in the office. Since we have been unable to obtain recent MCIR blood lead data for Flint kids in response to the lead in water concerns, we looked at all the blood lead levels that were processed through Hurley Medical Center from Jan 1, 2013. It turns out that most providers in Genesee county run their leads through our institution. Attached is a presentation that includes our striking pre-water switch (2013) and post-water switch results (2015) for kids less than 5 years living in the city of Flint (2.1% EBL to 4.0% EBL). Our pre and post periods included the same months considering the expected seasonal summer increase in lead levels. The results are most concerning for the kids that live in the zip codes where the water lead levels were found to be the highest (2.5% EBL to 6.3% EBL). No statistical change in %EBL for kids out of the city. Similar results were seen for kids less than 15 months. (Please do not share the presentation.)

Our sample size was large and our results were statistically significant; and we followed the same research methods conducted in the literature for similar lead exposures (most notably the DC lead in water issue). However, an even larger sample size which includes MCIR lead data would be very helpful as we continue to advocate for primary prevention. If we do have the MCIR data, for consistency and comparability to published research, we would like to conduct the analysis the same way as our above research. I am available via email or phone (cell [REDACTED]) if you have any questions about our data/methods/results and how best to move forward.

Thanks so much! Mona

Mona Hanna-Attisha MD MPH FAAP

Director, Pediatric Residency Program

Hurley Children's Hospital at Hurley Medical Center

Assistant Professor, Department of Pediatrics and Human Development

Michigan State University College of Human Medicine

Office: 810-262-7257

mhanna1@hurleymc.com

From: Mona Hanna-Attisha
Sent: Wednesday, September 16, 2015 11:28 AM

To: 'Scott, Robert L. (DCH)'; Lawrence Reynolds; Laura Carravallah; Dr. Lawrence Reynolds, M.D.
Cc: Peeler, Nancy (DCH); Lishinski, Karen (DCH); Emily Houk (emily@r2pconsultants.com)
Subject: RE: Lead level data

Thanks Bob for your willingness to get us this data!

At Hurley Children's Hospital, we have run similar analysis of BLL for all kids 5 and under, and then a focus on kids 15 months and under, with first time lead levels starting from 01/01/2013 to date of water source change 04/25/14 and then compared one year after water switch 4/25/15 to current. We looked at the change in mean BLL and the change in the % of EBL. Our sample size is representative of the high risk City of Flint population (zip codes 48501-48507), yet the sample size would be much greater with your MCIR data. To have more data will greatly help us advocate for prevention and educate our families.

Thank you in advance!

Mona Hanna-Attisha MD MPH FAAP
 Program Director Pediatric Residency
 Hurley Children's Hospital at Hurley Medical Center
 Michigan State University College of Human Medicine
 Department of Pediatrics and Human Development
 Mhanna1@hurleymc.com



From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Wednesday, September 16, 2015 10:48 AM
To: Lawrence Reynolds; Mona Hanna-Attisha; Laura Carravallah; Dr. Lawrence Reynolds, M.D.
Cc: Peeler, Nancy (DCH); Lishinski, Karen (DCH); Emily Houk (emily@r2pconsultants.com); Scott, Robert L. (DCH)
Subject: RE: Lead level data

Dr. Reynolds,

I'll be happy to slice up the data in that way, including the most recent months available. I'll be out of the office for the next few days, but will work on it when I get back.

It's my understanding that the State will develop a fact sheet as well as a tip sheet on lead-safe water use for parents. I'm not sure how they'll be made public.

Thanks,
 Bob

Robert L. Scott

Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

From: Lawrence Reynolds [mailto:lrey52@gmail.com]
Sent: Wednesday, September 16, 2015 10:31 AM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Mona Hanna-Attisha <MHanna1@hurleymc.com>; Laura Carravallah <lcarrav1@yahoo.com>; Dr. Lawrence Reynolds, M.D. <reynolds@mottchc.org>
Subject: Lead level data

Good morning Mr. Scott .

Thank you for your timely response. I have reviewed the graphs with our GCHD and Dr. Mona Hanna-Attisha of Hurley. Is it possible to stratify the data by age -under 15 months, 16 months to under 6 years of age , over 6 years. Also can we get the most recent data for 2015.

At this point we will work with our patients to educate them.

Breast feeding is first choice .

I understand different filters do different things for lead , and not all get lead clumps from leaching pipes so we will not emphasize them.

We will try to get WIC to cover bottled water and encourage using water from outside the city system

Our goal is to give the most consistent correct information.

Are there any plans for public service announcements from the state ?

I am asking you to cc my reynolds@mottchc.org email along with lrey52@ gmail so I can access from anywhere.

Lawrence Reynolds