

Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Friday, September 11, 2015 4:05 PM
To: Peeler, Nancy (DCH)
Subject: RE: childhood lead, question

Hi Nancy,

I don't see an issue with this. Seems pretty straightforward to me.

Angela

From: Peeler, Nancy (DCH)
Sent: Friday, September 11, 2015 2:43 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Subject: childhood lead, question
Importance: High

Hi Angela – we had a call from a pediatrician in Flint, who we know because he sits on our Provider Work Group. He asked for some childhood lead data, of the type that we had sent over to the Director, that was forwarded to the Governor's office. Erring on the side of caution, I wanted to check whether you are good with us sharing that same information with him. See attached. I realize that the Gov's office shared it with the group of Pastors they were meeting with, so it may be out in the public already. Anyway – if you see this and can give an opinion, I appreciate it.

Nancy

Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Thursday, September 24, 2015 1:16 PM
To: Peeler, Nancy (DCH); Bien, Stan (DCH); Scott, Robert L. (DCH)
Cc: Eisner, Jennifer (DCH); Lasher, GERALYN (DCH)
Subject: Flint Talking Points
Attachments: Flint Lead TP 092415.docx

Hi everyone,

With the Hurley press event at 3pm, can you please take a look at the following/attached talking points to make sure these are accurate and send me your edits?

Thank you.

-
- The results of the Hurley Children's Hospital are under review by the Michigan Department of Health and Human Services.
 - The analysis that Hurley conducted is different than the way MDHHS collects data regarding blood lead levels.
 - MDHHS is looking to see if we can replicate the results of the Hurley study to see how they achieved their results.

Differences in Analysis

- MDHHS data provides a much more robust picture of the entire blood lead levels for the Flint area, and specifically, accounts for data over the full course of the past five years.
- Looking at the past five years as a whole provides a much more accurate look at the seasonal trends of lead in the area.
- Seasonal exposure is higher in the summer for a variety of reasons including children playing outside in the soil, and when windows are open and lead paint is more likely to be in the air. This seasonal increase would be unrelated to the water system.
- Our data includes children from the entire city, including all medical facilities, rather than just Hurley, has a larger age group of children, and includes a much larger sample size.
- MDHHS data also looks specifically at the first test with elevated blood lead levels which provides a much more accurate picture of when and how first exposure occurred.
- The Hurley data includes a smaller sample size, much more limited time period (January-September of 2013 and 2015 only), and a smaller age group of children.

WIC Children

- For children with elevated blood lead levels that receive WIC benefits, they may be eligible to receive ready made formula with a test result that indicates that the child has an elevated blood lead level.
- WIC cannot cover bottled water.

Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Thursday, September 24, 2015 1:47 PM
To: Scott, Robert L. (DCH); Peeler, Nancy (DCH); Bien, Stan (DCH)
Cc: Eisner, Jennifer (DCH); Lasher, GERALYN (DCH)
Subject: RE: Flint Talking Points
Attachments: Flint Lead TP 092415.docx

Excellent. Thank you, Bob. I also spoke with Stan. The updated talking points are attached.

Angela

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 1:35 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>; Peeler, Nancy (DCH) <PeelerN@michigan.gov>; Bien, Stan (DCH) <biens@michigan.gov>
Cc: Eisner, Jennifer (DCH) <EisnerJ@michigan.gov>; Lasher, GERALYN (DCH) <lasherg@michigan.gov>
Subject: RE: Flint Talking Points

Angela,

One suggested change to the second bullet:

"The analysis that Hurley conducted is different from the way MDHHS has analyzed data regarding blood lead levels in Flint."

Another suggestion for the 5th bullet under Differences in Analysis:

"The MDHHS analysis looks specifically at the first elevated blood lead level for each child, which provides an accurate picture of when first exposure occurred."

Thanks,
 Bob

From: Minicuci, Angela (DCH)
Sent: Thursday, September 24, 2015 1:16 PM
To: Peeler, Nancy (DCH) <PeelerN@michigan.gov>; Bien, Stan (DCH) <biens@michigan.gov>; Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Eisner, Jennifer (DCH) <EisnerJ@michigan.gov>; Lasher, GERALYN (DCH) <lasherg@michigan.gov>
Subject: Flint Talking Points

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To: Peeler, Nancy (DCH)
Cc: Scott, Robert L. (DCH); Bien, Stan (DCH); Eisner, Jennifer (DCH); Lasher, GERALYN (DCH)
Subject: RE: Flint Talking Points

I personally think that's more inside baseball but if G or Jen thinks it would help to say, I'm fine adding it in.

Angela

From: Peeler, Nancy (DCH)
Sent: Thursday, September 24, 2015 1:54 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Cc: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Bien, Stan (DCH) <biens@michigan.gov>; Eisner, Jennifer (DCH) <EisnerJ@michigan.gov>; Lasher, GERALYN (DCH) <laserger@michigan.gov>
Subject: Re: Flint Talking Points

Do we want to add, in the first section, that MDHHS is working with Hurley to obtain approval for sharing a broader data set with Hurley for their review.

Sent from my iPad

On Sep 24, 2015, at 1:46 PM, Minicuci, Angela (DCH) <MinicuciA@michigan.gov> wrote:

Excellent. Thank you, Bob. I also spoke with Stan. The updated talking points are attached.

Angela

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 1:35 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>; Peeler, Nancy (DCH) <PeelerN@michigan.gov>; Bien, Stan (DCH) <biens@michigan.gov>
Cc: Eisner, Jennifer (DCH) <EisnerJ@michigan.gov>; Lasher, GERALYN (DCH) <laserger@michigan.gov>
Subject: RE: Flint Talking Points

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Thanks,
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To: Peeler, Nancy (DCH) <PeelerN@michigan.gov>; Bien, Stan (DCH) <biens@michigan.gov>; Scott, Robert L. (DCH) <ScottR9@michigan.gov>

Cc: Eisner, Jennifer (DCH) <EisnerJ@michigan.gov>; Lasher, GERALYN (DCH) <lasergh@michigan.gov>

Subject: Flint Talking Points

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Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Thursday, September 24, 2015 2:07 PM
To: Peeler, Nancy (DCH); Scott, Robert L. (DCH); Lasher, GERALYN (DCH); Eisner, Jennifer (DCH); Robinson, Mikelle (DCH); Moran, Susan (DCH); Hertel, Elizabeth (DCH)
Subject: FW: Flint lead data
Attachments: Pediatric Lead Exposure Flint Water 092415 FINAL.pdf

The Next Steps slide no longer recommends that the city declare a health advisory. It now says 'support city's health advisory'. If Flint will be issuing a health advisory, will Genesee County support this?

Angela

From: Murray, David (GOV)
Sent: Thursday, September 24, 2015 1:56 PM
To: Hollins, Harvey (GOV) <hollinsh@michigan.gov>; Lasher, GERALYN (DCH) <laserger@michigan.gov>; Minicuci, Angela (DCH) <MinicuciA@michigan.gov>; Eisner, Jennifer (DCH) <EisnerJ@michigan.gov>; Clement, Elizabeth (GOV) <clemente@michigan.gov>; Muchmore, Dennis (GOV) <muchmored@michigan.gov>; Agen, Jarrod (GOV) <AgenJ@michigan.gov>; Wurfel, Sara (GOV) <Wurfels@michigan.gov>; Wurfel, Brad (DEQ) <WurfelB@michigan.gov>; Tommasulo, Karen (DEQ) <TommasuloK@michigan.gov>
Cc: Biehl, Laura (GOV) <BiehlL@michigan.gov>; Brown, Jessica (GOV) <BrownJ53@michigan.gov>; Heaton, Anna (GOV) <HeatonA@michigan.gov>
Subject: Flint lead data

Team,

Here's the data that will be presented at the Hurley Hospital press conference at 3 p.m. As you'll see, they are pointing to individual children, a very emotional approach. Our challenge will be to show how our state data is different from what the hospital and the coalition members are presenting today.

Dave

----- Forwarded message -----

From: Andy Leavitt <aleavitt@senatedems.org>
Date: Thu, Sep 24, 2015 at 1:41 PM
Subject: Data
To: Angela Wittrock <awittrock@senatedems.org>

Hey Angela,

Sorry for the delay. Dr. Mona Hanna-Attisha wanted to make a few changes to one of her slides.

Andy

Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Thursday, September 24, 2015 2:49 PM
To: Peeler, Nancy (DCH)
Cc: Eisner, Jennifer (DCH)
Subject: Can you call us?

We're not clear about what data we can give out. Can you call us? 517-373-0860.

Angela Minicuci

Office of External Relations and Communications
Michigan Department of Health and Human Services
Office: (517) 241-2112
Mobile: PPI
minicucia@michigan.gov
www.michigan.gov/mdhhs

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Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Friday, September 25, 2015 1:13 PM
To: Scott, Robert L. (DCH); Peeler, Nancy (DCH)
Subject: FW: Flint follow-up

Importance: High

Hi Nancy and Bob,

The Detroit Free Press wants to do a bigger story about the issue of lead in Flint. I made it clear to her yesterday that we could not say the lead poisonings are related to the water, but she instead wants to do a story about the increase of overall lead poisonings in Flint between 12/13 and 14/15. Are either of you available to speak with her today?

Thank you,

Angela

From: Tanner, Kristi [mailto:ktanner@freepress.com]
Sent: Friday, September 25, 2015 12:16 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Subject: Flint follow-up

Hi Angela,

Thanks for the feedback yesterday. I took a look at the numbers last night that you sent over and the year over year increase between 13/14 and 14/15 is statistically significant $p < .05$

Can you ask you epidemiologist to confirm? Also, is this the first significant increase that Flint has seen for this cohort?

Thanks!

Kristi

(313) 222-8877 office

PPI cell

Children in Flint, less than 16 years of age, tested for lead

Children with Elevated BLL*			Children Tested**	
May 2010 - April 2011	168	0.043796	May 2010 - April 2011	3,836
2011-2012	153	0.036085	2011-2012	4,240
2012-2013	118	0.028379	2012-2013	4,158
2013-2014	95	0.023691	2013-2014	4,010
2014-2015	123	0.032106	2014-2015	3,831
May - August 2015	34	0.029746	May - August 2015	1,143

*Each child counted only once.

**Some children counted in more than one year.

September 24, 2015

Source: MDHHS Data Warehouse

Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Friday, September 25, 2015 1:36 PM
To: Peeler, Nancy (DCH)
Cc: Scott, Robert L. (DCH)
Subject: RE: Flint follow-up

Bob, I like what you had to say. That's basically what I told her, but she wants to hear it from someone other than a spokesperson ☺ Are you available for a call with her?

Angela

From: Peeler, Nancy (DCH)
Sent: Friday, September 25, 2015 1:20 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Cc: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: Re: Flint follow-up

I think Bob is the best person to speak to them about the lead data, if you are comfortable with that, Bob. My secret hope is that we can work in the fact that this pattern is similar to recent past. :)

Sent from my iPad

On Sep 25, 2015, at 1:12 PM, Minicuci, Angela (DCH) <MinicuciA@michigan.gov> wrote:

Hi Nancy and Bob,

The Detroit Free Press wants to do a bigger story about the issue of lead in Flint. I made it clear to her yesterday that we could not say the lead poisonings are related to the water, but she instead wants to do a story about the increase of overall lead poisonings in Flint between 12/13 and 14/15. Are either of you available to speak with her today?

Thank you,

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From: Tanner, Kristi [mailto:ktanner@freepress.com]
Sent: Friday, September 25, 2015 12:16 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Subject: Flint follow-up

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**Some children counted in more than one year.

September 24, 2015

Source: MDHHS Data Warehouse

Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Sunday, September 27, 2015 9:30 PM
To: Wells, Eden (DCH)
Cc: Lasher, Geralyn (DCH); Moran, Susan (DCH); Peeler, Nancy (DCH); Robinson, Mikelle (DCH); Hertel, Elizabeth (DCH); Eisner, Jennifer (DCH)
Subject: Re: State data confirms higher blood-lead levels in Flint kids

I've asked our lead epidemiologist to look at the data closer than what was in the charts to get a handle on this. The epi is Cristin Larder.

Sent from my iPhone

> On Sep 27, 2015, at 5:39 PM, Wells, Eden (DCH) <WellsE3@michigan.gov> wrote:

>

> Given not sure what % children tested, etc.

>

> Sent from my iPhone

>

>> On Sep 27, 2015, at 5:34 PM, Wells, Eden (DCH) <WellsE3@michigan.gov> wrote:

>>

>> Thanks--DFP is looking at tests positive/number of tests done-- not sure that this is a reliable measure used by our program. Await input from Nancy or Linda.

>>

>> Sent from my iPhone

>>

>>> On Sep 27, 2015, at 5:26 PM, Lasher, Geralyn (DCH) <lasherg@michigan.gov> wrote:

>>>

>>> Yes. We provided the graphs with the narrative bullet points.

>>>

>>> Sent from my iPad

>>>

>>>> On Sep 27, 2015, at 5:20 PM, Wells, Eden (DCH) <WellsE3@michigan.gov> wrote:

>>>>

>>>> Geralyn- were the graphs shown outside of MDHHS?

>>>>

>>>> Sent from my iPhone

>>>>

>>>>> On Sep 27, 2015, at 5:06 PM, Moran, Susan (DCH) <MoranS@michigan.gov> wrote:

>>>>>

>>>>> Sorry - hit send too soon.

>>>>> Copying Lynda and Corrine- not sure who in Epi or CLPPP has been point person on state's data.

>>>>>

>>>>> Sent from my iPhone

>>>>>

>>>>>> On Sep 27, 2015, at 2:11 PM, Lasher, Geralyn (DCH) <lasherg@michigan.gov> wrote:

>>>>>>

>>>>>> We will need help responding to what the Free Press is claiming in this article.

>>>>>>

>>>>> Sue-let us know who can get us this as early Monday as possible.

>>>>>

>>>>> State data confirms higher blood lead levels in Flint kids

>>>>>

>>>>> <http://www.freep.com/story/opinion/columnists/nancy-kaffer/2015/09/26/state-data-flint-lead/72820798/>

>>>>>

>>>>>

>>>>> Sent from my iPad

Peeler, Nancy (DHHS)

From: Minicuci, Angela (DCH)
Sent: Wednesday, September 30, 2015 8:48 AM
To: Fink, Brenda (DCH)
Cc: Moran, Susan (DCH); Wells, Eden (DCH); Travis, Rashmi (DCH); Peeler, Nancy (DCH); Said, Manal (DCH); Dunbar, Paulette Dobyns (DCH); Kostelec, Tiffany (DCH); Bien, Stan (DCH)
Subject: RE: Flint Water Situation
Attachments: Flint Lead TP 092415.docx

Hi Brenda,

Yes, our messaging is to support the recommendations from the local health department. We also have guidance related to WIC. Please see the attached talking points.

Thank you,

Angela

From: Wells, Eden (DCH)
Sent: Wednesday, September 30, 2015 8:43 AM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Subject: Fwd: Flint Water Situation

Sent from my iPhone

Begin forwarded message:

From: "Fink, Brenda (DCH)" <FinkB@michigan.gov>
Date: September 30, 2015 at 8:20:48 AM EDT
To: "Moran, Susan (DCH)" <MoranS@michigan.gov>, "Wells, Eden (DCH)" <WellsE3@michigan.gov>, "Travis, Rashmi (DCH)" <TravisR@michigan.gov>
Cc: "Peeler, Nancy (DCH)" <PeelerN@michigan.gov>, "Said, Manal (DCH)" <SaidM@michigan.gov>, "Dunbar, Paulette Dobyns (DCH)" <dunbarp@michigan.gov>, "Kostelec, Tiffany (DCH)" <KostelecT@michigan.gov>, "Bien, Stan (DCH)" <biens@michigan.gov>
Subject: RE: Flint Water Situation

I'm including Stan this time, as likely we'd want to be sure we're in sync w/WIC as well, given most of our moms/infants are in both programs.

Brenda Fink, A.C.S.W.
 Director, Division of Family and Community Health
 Michigan Department of Health and Human Services
 109 W. Michigan Ave.
 Lansing, MI 48933
 517-335-8863
 Fax: 517-335-8697
finkb@michigan.gov

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Sent: Wednesday, September 30, 2015 8:17 AM
To: Moran, Susan (DCH); Wells, Eden (DCH); Travis, Rashmi (DCH)
Cc: Peeler, Nancy (DCH); Said, Manal (DCH); Dunbar, Paulette Dobynes (DCH)
Subject: FW: Flint Water Situation
Importance: High

We are getting lots of questions here from our NFP and MIHP provders. We are thinking to ask all providers for those, and our other evidenced base HV provders that cover that geographic area to be sure to share the advisory the Mark V from the HD shared, and help the moms to understand what flushing the water means etc (remembering that written notices are not some moms primary way of understanding info). Any reason we should not go ahead and do so?

Brenda Fink, A.C.S.W.
 Director, Division of Family and Community Health
 Michigan Department of Health and Human Services
 109 W. Michigan Ave.
 Lansing, MI 48933
 517-335-8863
 Fax: 517-335-8697
finkb@michigan.gov

From: Moran, Susan (DCH)
Sent: Tuesday, September 29, 2015 8:14 PM
To: Miller, Corinne (DCH); Peeler, Nancy (DCH); Fink, Brenda (DCH); Scott, Robert L. (DCH); Miller, Corinne (DCH); Dykema, Linda D. (DCH); LyonCallo, Sarah (DCH); Scott, Jackie (DCH); Robinson, Mikelle (DCH); Miller, Mark (DCH); Priem, Wesley F. (DCH)
Cc: Grijalva, Nancy (DCH); Anderson, Paula (DCH); Rockefeller, Cheryl (DCH)
Subject: Flint Water Situation
Importance: High

Hi all- we have had a lot of communication coming from different sources and staff on Flint water situation- I would like to centralize all communication through Eden. I have asked Geralyn to communicate directly with Eden on any question/issues related to Flint water situation. Any e mail communication re: Flint water to Geralyn (or Nick/Nancy, communications office) should include cc to me and Eden. Thank you for your cooperation.

Please share with other staff that need to know.

Susan Moran MPH, Senior Deputy Director
 Population Health and Community Services Administration
 Capitol View Building
 201 Townsend St 6th Floor
 Lansing, MI
 48913
 Phone: 517 335 8024
 Fax: 517 335 9032
morans@michigan.gov

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, July 28, 2015 1:48 PM
To: Peeler, Nancy (DCH)
Subject: FW: Flint Testing and EBLs.xlsx

Nancy,

I said this morning I'd look to see if the distribution of EBLs in the July-September 2014 "spike" was any different from the typical distribution of EBLs in Flint. I compared totals by zip code vs totals by zip code from 2010 (BLs >=5). The pattern is very similar and is further evidence, I think, that the water was not a major factor here.

A	B	C	D
July-September 2010			
zip	# of EBL		
48503	11	16	% of total
48504	17	24	% of total
48505	19	27	% of total
48506	11	16	% of total
48507	8	11	% of total
48532		6	% of total
Total	70	100	% of total
CY 2010			
zip	# of EBL		
48503	68	21	% of total
48504	88	27	% of total
48505	79	24	% of total
48506	50	15	% of total
48507	30	9	% of total
48532	11	3	% of total
Total	326	100	% of total

Cristin is redoing her analysis with the extra two years of data. I assume it's OK to let her go ahead with that.

Bob

From: Larder, Cristin (DCH)
Sent: Tuesday, July 28, 2015 11:00 AM
To: Scott, Robert L. (DCH); Peeler, Nancy (DCH); McKane, Patricia (DCH)
Subject: RE: Flint Testing and EBLs.xlsx

Okay, thanks, Bob. I'll incorporate the previous years and put the new results into a publisher document with some description of what's going on in the chart.

We'll find out if this changes the results!

From: Scott, Robert L. (DCH)
Sent: Tuesday, July 28, 2015 10:15 AM
To: Larder, Cristin (DCH); Peeler, Nancy (DCH); McKane, Patricia (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

Cristin,

I can safely say I don't understand it without some explanation.

However, late yesterday Nancy and I decided to take a look two years farther back to see how they fit with the recent years. Please see attached, which I just finished this morning. Sorry I didn't have this for you yesterday before you did the analysis. Would this new information change the analysis?

Thanks,
 Bob

From: Larder, Cristin (DCH)
Sent: Tuesday, July 28, 2015 10:07 AM
To: Peeler, Nancy (DCH); McKane, Patricia (DCH)
Cc: Scott, Robert L. (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

Nancy and Bob,

Is the control chart clear enough, do you think? I could whip up a fact sheet with a description of what it shows, if you think it would help make it more digestible for our audience.

Cristin

From: Larder, Cristin (DCH)
Sent: Tuesday, July 28, 2015 9:25 AM
To: Peeler, Nancy (DCH); McKane, Patricia (DCH)
Cc: Scott, Robert L. (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

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From: Peeler, Nancy (DCH)
Sent: Monday, July 27, 2015 3:37 PM
To: McKane, Patricia (DCH)
Cc: Larder, Cristin (DCH); Scott, Robert L. (DCH)
Subject: Re: Flint Testing and EBLLs.xlsx

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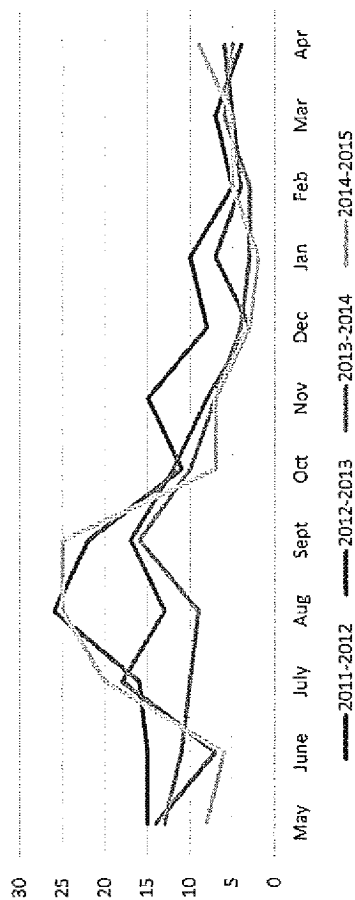
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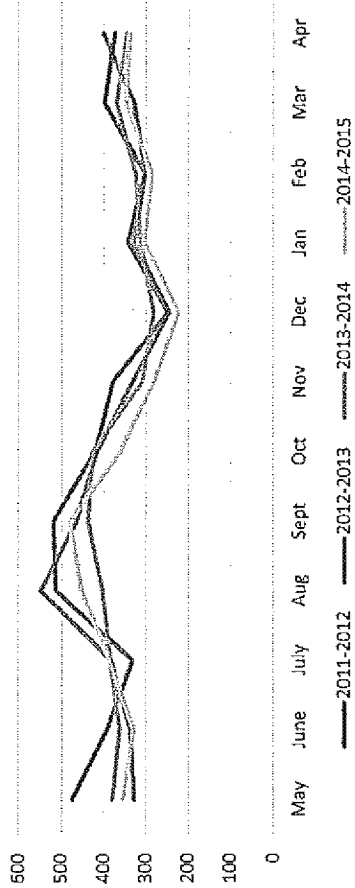
Nancy

<Flint Testing and EBLLs.xlsx>

City of Flint, Children less than 16 years of age
with First-Time Elevated Blood Lead Levels



City of Flint, Children less than 16 years of age
Tested for Lead Poisoning



	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2011-2012	15	15	16	26	22	11	15	8	10	5	7	4
2012-2013	14	7	18	13	17	12	8	3	7	4	5	6
2013-2014	13	11	10	9	16	10	7	4	3	3	6	5
2014-2015	8	6	20	25	25	7	7	3	2	5	5	9

	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2011-2012	474	393	332	513	520	420	379	249	343	303	399	375
2012-2013	328	338	383	550	464	417	332	246	328	303	328	402
2013-2014	380	363	385	404	438	427	310	283	313	325	371	346
2014-2015	356	329	386	452	480	361	283	224	305	287	348	339

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, July 28, 2015 10:15 AM
To: Larder, Cristin (DCH); Peeler, Nancy (DCH); McKane, Patricia (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx
Attachments: Flint Testing and EBLLs_2.xlsx

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<Flint Testing and EBLs.xlsx>

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, July 28, 2015 2:28 PM
To: Peeler, Nancy (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

No, sorry, I mislabeled the top one. Should say "July-September 2014."

From: Peeler, Nancy (DCH)
Sent: Tuesday, July 28, 2015 2:26 PM
To: Scott, Robert L. (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

So this is 2010 data, rather than 2014 data?

From: Scott, Robert L. (DCH)
Sent: Tuesday, July 28, 2015 1:48 PM
To: Peeler, Nancy (DCH)
Subject: FW: Flint Testing and EBLLs.xlsx

Nancy,

I said this morning I'd look to see if the distribution of EBLLs in the July-September 2014 "spike" was any different from the typical distribution of EBLLs in Flint. I compared totals by zip code vs totals by zip code from 2010 (BLLs >=5). The pattern is very similar and is further evidence, I think, that the water was not a major factor here.

A	B	C	D
July-September 2010			
zip	# of EBLL		
48503	11	16	% of total
48504	17	24	% of total
48505	19	27	% of total
48506	11	16	% of total
48507	8	11	% of total
48532		6	% of total
Total	70	100	% of total
CY 2010			
zip	# of EBLL		
48503	68	21	% of total
48504	88	27	% of total
48505	79	24	% of total
48506	50	15	% of total
48507	30	9	% of total
48532	11	3	% of total
Total	326	100	% of total

Cristin is redoing her analysis with the extra two years of data. I assume it's OK to let her go ahead with that.

Bob

From: Larder, Cristin (DCH)
Sent: Tuesday, July 28, 2015 11:00 AM
To: Scott, Robert L. (DCH); Peeler, Nancy (DCH); McKane, Patricia (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

Okay, thanks, Bob. I'll incorporate the previous years and put the new results into a publisher document with some description of what's going on in the chart.

We'll find out if this changes the results!

From: Scott, Robert L. (DCH)
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Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:09 PM
To: Peeler, Nancy (DCH); Lishinski, Karen (DCH); Priem, Wesley F. (DCH)
Subject: Flint water study
Attachments: Rapid Proposal Final.pdf

Nancy, Karen and Wes,

I'm passing this along as follow-up to our previous attention to the Flint water changeover situation. The attached was submitted to me along with a request for de-identified data, which should be no problem.

When you have a few minutes you might want to take a look at it. Sounds like there might be more to this than what we learned previously. Yikes!

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

A. Project Summary

Overview: Flint, MI, is currently suffering from a “perfect storm” attributable to out-of-control corrosion of its potable water distribution system. The corrosion is undermining water affordability for residents, financial viability of city government, water aesthetics, and hygiene/sanitation as revealed in local and national news reporting. We *hypothesize* that these circumstances will also create severe chemical/biological health risks for Flint residents, including elevated levels of lead and opportunistic premise plumbing pathogens (OPPPs) in drinking water. Preliminary data collected from a home of a lead poisoned child in Flint has revealed extraordinarily high levels of lead, with average concentrations over 20 minutes of water use exceeding 2,000 ppb (> 200 times the World Health Organization allowable levels for lead in potable water).

The main *objectives* of this research are to: 1) compare levels of chlorine, iron, fecal indicator bacteria, OPPPs, and corrosion-inducing bacteria present in water mains of a distribution system with uncontrolled corrosion (Flint) versus surrounding cities/counties still using non-corrosive water, 2) profile OPPPs occurrence in hot and cold potable water systems at these same locations, and 3) determine if there is evidence of elevated lead in Flint homes, and, if so, forensically determine the links to iron corrosion. Our team is uniquely qualified to do this work given our just published peer reviewed research on this subject and our extensive collaborations with key stakeholders in Flint.

Intellectual Merit: The four elements of the “perfect storm” currently undermining water quality (and possibly public health) in Flint include: a) chronic underinvestment in water infrastructure, b) underappreciation of the role of corrosion control in sustaining urban potable water systems, c) increased corrosion due to higher chloride in Flint’s new source water, and d) failure to appropriately monitor for lead and OPPPs. The latter two factors are amongst the most important health problems arising in modern potable water systems. The high rates of corrosion occurring in Flint are releasing high levels of iron to water and consuming chlorine disinfectant, which our most recent laboratory testing has indicated will increase lead release to water and growth of OPPPs in cold and hot water plumbing systems. The unfortunate but unique opportunity offered by Flint’s current situation, provides an ideal opportunity to field test our recent discoveries regarding potentially adverse consequences of iron corrosion on chemical/microbiological water quality at field rather than laboratory scale.

Broader Impacts: This RAPID grant will directly assist residents of Flint in assessing the current safety of their potable water supply. If the results support recently issued public assurances regarding safety of water, the current problems in Flint can be considered mainly of aesthetics and perception due to very distasteful or discolored water. However, if sampling reveals widespread problems, the public will learn of the potential health threat. Since elements of the “perfect storm” afflicting Flint are occurring at some level in many other financially stressed U.S. urban centers with decaying drinking water infrastructure, this Rapid Response Research (RAPID) grant also provides an unprecedented opportunity to advance fundamental scientific and practical understanding at this emerging nexus of infrastructure-environmental engineering-public health. The general results and approach used herein can inform residents and managers of other U.S. cities, who will soon be dealing with similar problems associated with failing potable water infrastructure exacerbated by increased chloride in water due to excessive use of road salt and rising sea levels. The research also provides a compelling case study in *Citizen Science*, since the experiences of Flint parents in monitoring their children’s health and environmental exposures was a trigger for our preliminary testing, and Flint consumers will be scientifically empowered by participating in fundamental research relying on collection of samples from their homes and residences. There is also a social justice implication of the research, in that these results can help inform the current policy debate regarding strategies for dealing with cities that have gone bankrupt, as well as the discussion of access to safe and affordable drinking water as a basic human right.

RAPID: Synergistic Impacts of Corrosive Water and Interrupted Corrosion Control on Chemical/Microbiological Water Quality: Flint, MI

1. Problem Statement and Objectives

Flint, MI, is currently suffering from a “perfect storm” due to out-of-control corrosion of its potable water distribution system, undermining the well-being of the community including water affordability for residents, financial viability of city government, water aesthetics, and hygiene/sanitation.¹⁻¹³ Flint’s problems began in April 2014, when emergency managers hired to deal with the city’s fiscal crisis determined they could save money by switching to a local river water source as opposed to purchasing water from Detroit (Table 1). As a result of the change in source water, the Larson Iron Corrosion Index was raised from 0.54 (low corrosion) to 2.3 (very high corrosion) and the chloride to sulfate mass ratio (CSMR) index for lead corrosion increased from 0.45 (low corrosion) to 1.6 (very high corrosion). Concurrently, the managers and state primacy agency attempted to save even more money by not feeding an orthophosphate corrosion inhibitor to the water supply (Table 1).

Not surprisingly, the combined effect of more corrosive water and removal of the corrosion inhibitor unleashed unprecedented corrosion in the water main distribution system with cascading personal, economic, and public health consequences to Flint as tracked by news reports and mandatory chemical/biological monitoring of water in the distribution system mains.¹⁻¹⁴ *Our recent research also predicts that these circumstances will potentially create severe chemical/biological health risks for residents, due to impacts on water within building (premise) plumbing systems that include elevated levels of lead and opportunistic premise plumbing pathogens (OPPPs).*¹⁵⁻¹⁸ Because the factors impacting Flint are also occurring at some level in many other financially-stressed U.S. urban centers with decaying drinking water infrastructure, this *Rapid Response Research (RAPID) grant provides an unprecedented opportunity to advance fundamental scientific and practical understanding at this emerging nexus of infrastructure-environmental engineering-public health.* We view August-September 2015 as the ideal time to first sample in Flint, as more than 16 months of uncontrolled corrosion have occurred and the water remains near its seasonal peak temperature, maximizing the likelihood of serious problems with lead and OPPPs if they exist.

Our key hypothesis is that the rapid corrosion of iron water mains will dramatically increase lead release to water and growth of OPPPs as measured in consumers’ homes. Mechanistically, higher iron corrosion produces both higher iron in water and lower levels of free chlorine, both of which dramatically increased lead release and OPPPs regrowth in our just published laboratory research utilizing simulated distribution systems.¹⁵⁻¹⁹ The *main objectives of this research* are to: 1) compare levels of chlorine, iron, fecal indicator bacteria, OPPPs, and corrosion-inducing bacteria present in water mains of a distribution system with uncontrolled corrosion (Flint) versus controlled corrosion in surrounding cities/counties still using non-corrosive Detroit water, 2) profile hot and cold potable water systems at the same sampling locations in #1 for OPPPs, and 3) determine if there is evidence of elevated lead in Flint homes, and, if so, forensically determine the links to iron corrosion.^{15, 17-20} The unfortunate but unique opportunity offered by Flint’s current situation provides an ideal opportunity to field test our recent discoveries regarding adverse consequences of iron corrosion on OPPPs and lead concentration at the tap.

Table 1. Water quality parameters for drinking water supplied in Flint, MI before and after the April 2014 switch

Parameter	Before ¹	After ²
pH	7.38	7.61
Hardness (mg/L as CaCO ₃)	101	183
Alkalinity (mg/L as CaCO ₃)	78	77
Chloride (mg/L)	11.4	92
Sulfate (mg/L)	25.2	41
CSMR ³	0.45	1.6
Inhibitor (mg/L as P)	0.35	NONE
Larson Ratio ⁴	0.5	2.3

¹Source: City of Flint Monthly Operation Report, June 2015. Available from www.cityofflint.com

²Source: DWSD 2014 Water Quality Report. Available from www.dwsd.org

³A measure of corrosivity to lead; a value > 0.5 is a critical trigger [10]

⁴A measure of corrosivity to mild steel and iron; corrosion rate increases linearly with Larson Ratio [8]

2. Review of Local Events and Intellectual Merit

Local Impacts. After the switch of water sources, residents of Flint were immediately subject to an outbreak of corrosion-related drinking water problems including flooding from large water main breaks and reported health ailments.¹⁻⁶ General Motors, a prime customer of the water system, reported that the new water was severely corroding auto parts on its assembly line and had to begin importing water, costing the city \$400,000 in lost revenue.

⁹ The PI was also alerted by an Environmental Protection Agency volunteer to a case of childhood lead poisoning in a Flint home that was certified as “lead free.”⁴ Samples collected from the home exhibited classic “red water” that is occurring throughout the city (Figure 1), along with the



Figure 1. Drinking water samples collected from home of a child who was lead poisoned by Flint water.

highest sustained levels of lead in drinking water that we have encountered in over 25 years of research on the subject. Specifically, in 30 samples collected over a period of 25 minutes flushing at the kitchen faucet, lead concentrations averaged over 2,000 ppb and were as high as 13,000 ppb. For perspective, these levels are more than 200-1,300 times higher than World Health Organization standards (10 ppb) and several even exceeded the EPA criterion for “hazardous waste” of 5,000 ppb Pb. The city has also reported unspecified economic losses due to water main breaks and water losses through leaks.^{3,7,11-12}

The corrosion problems have also had cascading impacts on health parameters monitored under federal regulations. Because the corrosion is rapidly consuming chlorine disinfectant in the water, the city violated EPA limits for *E. coli*.⁵⁻⁶ The detaching iron rust also has the potential to expose consumers to other contaminants that pose a serious public health risk, including arsenic¹⁴ and lead that have accumulated in pipes or sorbed to iron surfaces.¹⁵⁻¹⁶ Health effects reported by residents since the switch include skin rashes, hair loss, vomiting, copper poisoning, and the one confirmed case of lead poisoning.^{2-4,7,13} However, the relatively small number of cases reported to date almost certainly underestimates the full extent of the problem. In response to the sampling showing high lead, the authorities who made the decision to switch water sources and stop adding corrosion inhibitor publicly stated that “anyone who is concerned about lead in the drinking water in Flint can relax” and that the water is safe,⁴⁴ but refuse to sample consumers’ water without pre-flushing the plumbing for at least 5 minutes the night before sampling. The latter practice is known to miss lead in water problems.

We are also concerned about possible health effects that have not yet been investigated. For example, in March 2015 Region 5 EPA was provided reports of higher incidence of Legionnaires’ disease associated with bacteria growth in premise plumbing in the Flint area.²¹ Legionnaires’ disease has recently been acknowledged to be the primary source of waterborne disease outbreaks (and associated deaths) in the U.S.²² Despite that acknowledged risk, there is currently no required monitoring for this important pathogen in consumers’ homes, where it proliferates and can lead to human exposure and infection in showers.²²

Intellectual Merit. The four elements of the “perfect storm” currently undermining water quality (and possibly public health) in Flint include: a) chronic underinvestment in water infrastructure, b) underappreciation of the role of corrosion control in sustaining urban potable water systems, c) increased corrosivity of water sources nationally due to rising chloride levels from anthropogenic pollution and/or rising sea levels, and d) failure to appropriately monitor for lead and OPPPs, which are two of the most important modern-day public health problems arising in building plumbing systems.

- a) **Chronic Underinvestment in Water Infrastructure.** A large fraction of the nation’s potable water infrastructure is on the verge of failure, and this problem has been repeatedly voted by

D. Project Description

members of the American Society of Civil Engineers (ASCE) as the most urgent societal infrastructure challenge with an overall condition grade of "D".^{23,24} Many water main distribution systems are reaching the end of their design lifetime (60-95 years), with water main breaks currently at a rate of 240,000 per year nationally and rising.^{25,26} Aside from obvious public health implications associated with compromised delivery of uncontaminated drinking water to the tap, failure events can cause property damage and water loss through leaks.²⁷ Like many post-industrial manufacturing centers, Flint has a very large potable distribution system constructed to sustain a large consumer and industrial base that no longer exists. The projected cost to upgrade the distribution system is \$1.5 billion dollars,²⁸ which would translate to an unbearable cost of \$50,000 per existing customer in Flint.²⁸

- b) **Under-appreciation of the role of corrosion control in sustaining potable water systems.** Estimates by ASCE, the American Water Works Association (AWWA), the Environmental Protection Agency (EPA), the Water Infrastructure Network (WIN), and the National Academy of Corrosion Engineers (NACE) suggest that direct costs of water pipeline corrosion range between \$8 billion - \$36 billion annually and indirect costs are much higher.²⁷ Leaks result in 7 billion gallons of lost water each day with associated revenue losses of $\approx$ \$3 billion per year for U.S. utilities.²⁹ Problems with leaking potable water plumbing systems in buildings (i.e. premise plumbing) also cost consumers billions of dollars each year.^{30,31} Water utilities can reduce costs of potable water system corrosion and extend the lifetime of these invaluable assets by adding corrosion inhibitors, such as orthophosphate, to the water. Prior research using a relatively low corrosivity source water determined that each dollar invested in corrosion control produced more than \$5 dollars in financial savings due to reduced corrosion damage and extended lifetime of pipeline infrastructure.³² In Flint, the short-sighted decision to reduce chemical costs by removing the corrosion inhibitor and introducing corrosive water to the system may have produced tens if not hundreds of millions of dollars in corrosion damages to its existing potable water distribution system. We are also aware of many other utilities that are cutting back on their corrosion inhibitor doses due to cost-cutting pressures.
- c) ***Increased corrosivity of water sources nationally due to rising chloride levels from anthropogenic pollution and/or rising sea levels.*** Chloride levels in drinking water are rising nationally in surface water due to use of road salt and seawater intrusion in coastal regions. Road salt use in winter has risen to 137 lbs per year for every American, with a doubling of salt application from 1990 to 2014 (10 vs. 22 million tons) associated with a doubling of chloride levels in northern U.S. waters as monitored by the USGS.^{33,34} There is documented concern about the damage of salt application to infrastructure such as roads and bridges,³⁵ but rising salt levels in the Potomac (due to road salt) in 2015 also have triggered a spike in consumer complaints of red or brown water from their main distribution system.^{36,37} and we are currently working with a utility in Brick, NJ that is reporting high lead in consumers' water due to higher chloride from rising sea levels near their intake as well as road salt use.³⁸⁻⁴⁰ The higher corrosivity of water in Flint due to higher chloride (Table 1), therefore provides an interesting "acute" case study of higher chloride impacts that can shed light on these important national trends.
- d) ***Failure of utilities and regulatory agencies to take responsibility for the two most important modern day public health problems arising in building plumbing systems (i.e., lead and OPPPs).*** For ten years EPA has acknowledged that utilities are collecting samples in a manner that "misses" worst case lead in water,⁴¹⁻⁴³ and to date they have not required utilities to change monitoring practices to better reveal problems. The EPA LCR sampling protocols have been under review since 2008 and the EPA is expected to issue new requirements sometime in 2016. Hence, sampling in Flint without "pre-flushing" to reduce lead, as revealed by the EPA

D. Project Description

volunteer,⁴ could inform modifications to the EPA LCR. Likewise, EPA's current regulations on *Legionella* consider only levels that might be present in water leaving the treatment plant, where it is least likely to be present, and do not yet require monitoring at the point of entry into homes or within buildings where *Legionella* is most likely to be present and cause disease.²¹ Our proposed sampling for *Legionella* at these locations can therefore inform future regulation and distribution system management policies for dealing with this emerging public health risk.^{19,22}

In summary, this proposed RAPID grant characterizing the occurrence of chemical/biological problems in Flint, MI homes explores a newly emerging nexus between degrading infrastructure-environmental engineering-public health that can provide insight into problems facing many cities all over the United States.

3. Approach

The *RAPID grant objectives* will be achieved through three phases of sampling, using analytical methods in routine use by the project team, as follows:

Phase 1. Compare levels of chlorine, iron, fecal indicator bacteria, OPPPs, and corrosion-inducing bacteria present in water mains of a distribution system with uncontrolled corrosion (Flint) versus controlled corrosion in surrounding cities/counties still using non-corrosive Detroit water. A team including the PI and at least 3 graduate students will travel to Flint and stay 3-7 days in mid-August 2015, to collect 8 distribution system samples from surrounding cities still using Detroit water, and to also sample Flint's 8 distribution system monitoring locations (Figure 1). We will stay in two hotel rooms, one located in Flint and one in a surrounding location on Detroit water, to conveniently collect samples for free chlorine at 2 hour intervals expected to correspond to lowest and highest daily demand. All of these analyses will be conducted using standard methods with the exception of testing for corrosion-inducing bacteria which will be conducted with Biological Activity Reaction Test (BART) kits. BARTs are standardized colorimetric culture kits that are semi-quantitative and include testing for Sulfate-Reducing Bacteria (SRB), Heterotrophic Aerobic Bacteria, Heterotrophic Anaerobic Bacteria, Denitrifiers, Slime Forming Bacteria, and Acid Producing Bacteria (APB). It is hypothesized that the Flint waters will have much lower levels of free chlorine, higher levels of iron, corrosion-inducing bacteria, and fecal indicator bacteria than samples collected from locations still on Detroit water.

Phase 2. Profile building hot and cold water plumbing systems for OPPPs at the same sampling locations used in Phase 1.

Protocols used previously to sample for a suite of OPPPs and two host protozoa^{18,20} in hot and cold water from taps and biofilms of buildings using quantitative Polymerase Chain Reaction (q-PCR) analysis, will be used to profile the hot and cold water systems for human pathogens at the same locations tested in Phase 1. Specifically, target microbes including *Legionella pneumophila*, *M. avium*, *P. aeruginosa*, *Acanthamoeba* and *Vermamoeba vermiformis* will be quantified by qPCR, and hot water samples will be cultured for *Legionella* and

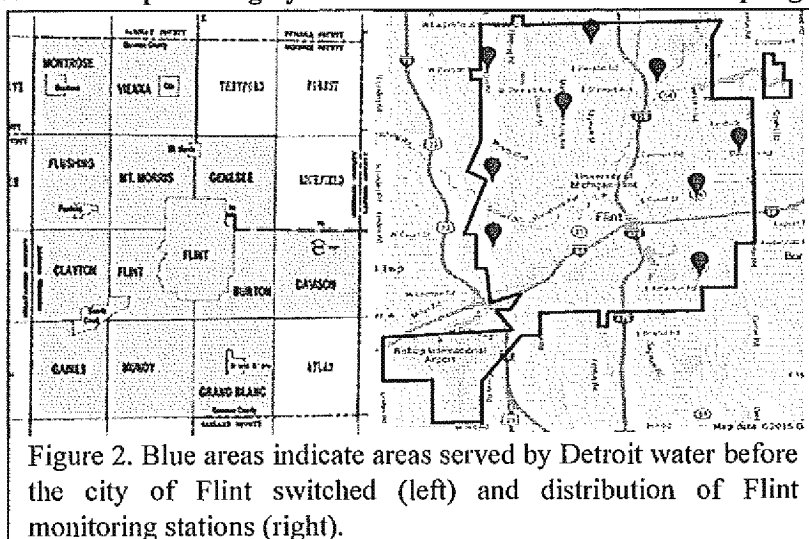


Figure 2. Blue areas indicate areas served by Detroit water before the city of Flint switched (left) and distribution of Flint monitoring stations (right).

D. Project Description

Mycobacteria from each location. Samples collected for microbial analysis and fecal indicator bacteria (Phase 1) will be overnight shipped from Michigan via cold-pack using protocols developed by the project team on NSF Project CBET-1438328. In Flint, for comparison, at least three additional privately owned homes will be sampled for OPPPs using the same protocols as for the public buildings.

Phase 3. Determine if there is evidence of elevated lead in Flint homes. We will coordinate with several local citizen groups including the American Civil Liberties Union (ACLU), Concerned Pastors for Social Action, and others to sample homes in Flint for lead in water. We will prepare 300 sampling kits with instructions, to collect water samples according to standard EPA LCR protocols for shipment to community groups. Each kit will contain three bottles to sample water after standard water stagnation (> 6 hours) at typical-use flow rates, including 1) first draw standard LCR (1 liter), 2) 45 second flushing 0.5 liter sample (targeting the lead service line, if present), and 3) 5 minutes of flushing 0.25 liter sample. Each kit will have a sample form to fill out information including 1) name of person collecting sample, 2) age of home (if known), 3) mailing address of home sampled, and 4) date of sample collection. A phone number will be provided of a member of the Virginia Tech team, who can answer questions that residents have about the instructions (if any). Residents will be instructed to return the sampling kits to a centralized location according to procedures that best suit each citizen group. The sample kits will then be put into boxes provided by the project team, and shipped back to Virginia Tech with the postage paid by the RAPID grant. Assuming a response rate of 33%, 300 samples ($= 0.33 \times 300 \times 3$ bottles per kit) will be analyzed for lead, iron, copper and other constituents using the PI's Inductively Coupled Plasma Mass Spectrometer (ICP-MS). All returned kits will be analyzed, and results will be summarized in a letter to each consumer to be sent out within 1 month of receiving the samples. We will provide a phone number of a senior research scientist (Dr. Jeff Parks) that the residents can call to ask questions about their results if they have them and compile the results in a summary form for research publications and public outreach.

4. Project Management and Prior NSF Support

The senior project team (Edwards, Pruden, Falkinham) has collaborated together extensively and has a strong record of success. They will be assisted in leading the project by Dr. Brandi Clark (former NSF graduate fellow) who is a recent graduate of Virginia Tech (2015). Edwards and Clark will coordinate the Flint site visit and the lead survey. Another NSF graduate fellow (Emily Garner, formerly Emily Lipscomb) who is currently co-advised by Pruden/Edwards will assist the Flint site visit team and coordinate biological sample analysis and shipments. Pruden and Falkinham will assist in the data analysis, interpretation and write-up of the results.

5. Broader Impacts

In addition to improving practical and scientific understanding related to two of the most important problems associated with potable water and health in consumer homes (i.e., lead and OPPPs), this RAPID grant will directly assist residents of Flint in assessing the safety of their potable water supply. The results and approach used herein can inform residents and managers of other U.S. cities who will soon be dealing with similar problems associated with failing potable water infrastructure and increased corrosivity of potable water. Phase 3 of this research also provides an interesting case study in *Citizen Science* as a tool to advance scientific understanding, policy, and public health, because consumers are actively collecting samples from their homes and will be participating in National Science Foundation research. The work also has social justice implications, as the plight of Flint residents has already received national attention, and results can inform the current debate regarding access to safe, affordable water as a "right" for Americans in U.S. cities.

REFERENCES

1. Fonger, R. Flint DPW director says water use has spiked after hundreds of water main breaks. April 22, 2015. Accessed 7-26-2015 at http://www.mlive.com/news/flint/index.ssf/2015/04/flint_dpw_director_says_water.html.
2. Associated Press. Flint city councilman: 'We got bad water'. January 14, 2015. Accessed 7-24-2015 at <http://www.freep.com/story/news/local/michigan/2015/01/14/flint-water-resident-complaints/21743465/>.
3. Erb, R. Who wants to drink Flint's water? January 22, 2015. Accessed 7-24-2015 at <http://www.freep.com/story/news/local/michigan/2015/01/22/water-woes-latest-hit-flint/22193291/>.
4. Guyette, C. Scary: Leaded Water and One Flint Family's Toxic Nightmare. July 9, 2015. Accessed 7-24-2015 at http://www.deadlinedetroit.com/articles/12697/scary_leaded_water_and_one_flint_family_s_toxic_nightmare#.VbLvmvIViko.
5. Lockwood, Andrews, & Newnam Inc., Operational Evaluation Report: City of Flint (Trihalomethane Formation Concern). November 2014. Accessed 7-24-2015 at <http://cityofflint.com/wp-content/uploads/Operational-Evaluation-Report.pdf>
6. U.S. Environmental Protection Agency. Internal Memo: High Lead Levels in Flint, Michigan -- Interim Report. June 24, 2015. Accessed 7-24-2015 at <http://www.aclumich.org/sites/default/files/file/EPAWaterReport062415.pdf>.
7. Smith, M. A Water Dilemma in Michigan: Cloudy or Costly? March 25, 2015. Accessed 7-24-2015 at <http://www.nytimes.com/2015/03/25/us/a-water-dilemma-in-michigan-cheaper-or-clearer.html>.
8. Larson, T. E. and R.V. Skold. Laboratory Studies Relating Mineral Quality of Water to Corrosion of Steel and Cast Iron. *Corrosion* (1958). 14(6): p. 43-46.
9. Fonger, R. GM's decision to stop using Flint River water will cost Flint \$400,000 per year. October 14, 2014. Accessed 7-24-2015 at http://www.mlive.com/news/flint/index.ssf/2014/10/gms_decision_to_stop_using_fli.html.
10. Nguyen, C., et al., Impact of Chloride:Sulfate Mass Ratio (CSMR) Changes on Lead Leaching in Potable Water. 2010, Denver, CO: Water Research Foundation.
11. Longley, K. Massive water leak, theft contribute to Flint water rate increases, officials say. May 10, 2012. Accessed 7-24-2015 at http://www.mlive.com/news/flint/index.ssf/2012/05/flint_officials_water_leakage.html.
12. Fonger, R., Flint's built-in water rate increase of 6 percent won't fly, say some on City Council. February 25, 2015. Accessed 7-24-2015 at http://www.mlive.com/news/flint/index.ssf/2015/02/flint_water_rates_headed_higher.html
13. Abbey-Lambertz, K. Reverend Compares Michigan City's Drinking Water Issues to the Holocaust. March 6, 2015. Accessed 7-24-2015 at http://www.huffingtonpost.com/2015/03/05/flint-water-drinking-clean-tthm_n_6810368.html
14. Lytle, D.A., T.J. Sorg, and C. Frietch, Accumulation of Arsenic in Drinking Water Distribution Systems. *Environmental Science & Technology*, 2004. 38(20): p. 5365-5372.
15. Masters, S., and M. Edwards. Increased Lead in Water Associated with Iron Corrosion. *Environmental Engineering Science*, (2015), 32 (5), 361-369.
16. Masters, S.M., Wang, H., A. Pruden and M. Edwards. Redox Gradients in Distribution Systems Influence Water Quality, Corrosion, and Microbial Ecology. *Water Research*, (2015), DOI: 10.1016/j.watres.2014.09.048.
17. Wang, H., Masters, S., Edwards, M.A., Falkinham, J.O. III, and A. Pruden. Effect of Disinfectant, Water Age, and Pipe Materials on Bacterial and Eukaryotic Community Structure in Drinking Water Biofilm. *Environmental Science & Technology*. dx.doi.org/10.1021/es402636u.
18. Wang, H., S. Masters, Y Hong, J. Stallings, J.O. Falkinham, M. Edwards and A. Pruden. Effect of disinfectant, water age, and pipe material on occurrence and persistence of Legionella, mycobacteria,

- Pseudomonas aeruginosa*, and two amoebas. *Environmental Science & Technology* 46 (21), 11566-11574 (2012).
19. Wang, H., Masters, S.; Falkinham, J.O.; Edwards, M.; and A. Pruden. Distribution System Water Quality Affects Responses of Opportunistic Pathogen Gene Markers in Household Water Heaters. *Environmental Science & Technology*. (2015), DOI: 10.1021/acs.est.5bo538
 20. Wang, H., M. Edwards, J. Falkinham and A. Pruden. Molecular Survey of the Occurrence of *Legionella* spp., *Mycobacterium* spp., *Pseudomonas aeruginosa*, and *Amoeba* Hosts in Two Chloraminated Drinking Water Distribution Systems. (2012), *Applied and Environmental Microbiology*. 78(17) 6285-6294.
 21. Del Toral, Personal Communication. Timeline of Events in Flint, MI (2015).
 22. Pruden A, Edwards MA, Falkinham III, JO, Arduino M, Bird J, Birdnow R, Bédard E, Camper A, Clancy J, Hilborn E, Hill V, Martin A, Masters S, Pace NR, Prevost M, Rosenblatt A, Rhoads W, Stout JE, Zhang Y. (2013) Research needs for opportunistic pathogens in premise plumbing: Methodology, microbial ecology, and epidemiology. Water Research Foundation Project 4379 Final Report. Water Research Foundation. Denver, CO, 188 pages.
 23. American Society of Civil Engineers (ASCE). (2009) "Report Card for America's Infrastructure." Washington, DC. Accessed on 05/05/2010 at <http://www.infrastructurereportcard.org>.
 24. American Society of Civil Engineers (ASCE). (2011) "Failure to Act: The Economic Impact of Current Investment Trends in Water and Wastewater Treatment Infrastructure." Washington, DC.
 25. US Environmental Protection Agency (EPA). (2010) "Addressing the Challenge Through Science and Innovation." Aging Water Infrastructure Research, Office of Research and Development, Washington DC.
 26. Walker, F. G. and Schaefer, G. M. (2009) "White Paper: Corrosion and Cracks in Water Pipes: Can We See Them Sooner?" Bartron Medical Imaging Inc., Largo Maryland.
 27. US Environmental Protection Agency (EPA). (2002) "The Clean Water and Drinking Water Infrastructure Gap Analysis." Office of Water, Washington DC.
 28. City of Flint Water System Facts. Accessed 7-26-2015 at <https://www.cityofflint.com/wp-content/uploads/Water-System-Facts.pdf>.
 29. US Federal Highway Administration (FHWA). (2002) "Corrosion Costs and Preventive Strategies in the United States." Publication No. FHWA-RD-01-156.
 30. Scardina, P. and Edwards, M. (2008) "Investigation of Copper Pipe Failures at Location I." Assessment of Non-Uniform Corrosion in Copper Piping, American Water Works Association Research Foundation, Denver, CO.
 31. Bosch, D. and Sarver, E. (2007) "Economic Costs of Pinhole Leaks and Corrosion Prevention in U.S. Drinking Water Plumbing." In Proceedings of American Water Works Association Annual Conference and Exhibition, Charlotte, NC.
 32. Ryder, R.A. (1980). The Costs of Internal Corrosion in Water Systems. *Jour. AWWA*, 72(5), pp. 267.
 33. Strombert, J. What Happens to All the Salt We Dump on the Roads. *Smithsonian.com*. (2014). Accessed 07-26-2015 at <http://www.smithsonianmag.com/ist/?next=/science-nature/what-happens-to-all-the-salt-we-dump-on-the-roads-180948079/>
 34. Corsi, S. R., De Ciccio, L.A., Lutz, M. A., and R. M Hirsch. River chloride trends in snow-affected urban-watersheds: increasing concentrations outpace urban growth rate and are common among all seasons. (2015), *Science of the Total Environment*, 508, 488-497.
 35. Dindorf, C., and C. Fortin. The Real Cost of Salt Use for Winter Maintenance in the Twin Cities Metropolitan Area. Minnesota Pollution Control Agency. October 2014. Accessed 07-26-2015 at <http://www.pca.state.mn.us/index.php/view-document.html?id=21766>
 36. Wheeler, T. (2015), Salt Concentrations High in 2 Md. Rivers. *Baltimore Sun*. January 2, 2015. Accessed 07-26-2015 at <http://www.baltimoresun.com/features/green/blog/bs-hs-salty-streams-20150102-story.html>

37. Shaver, K. (2015), The snow brought out the salt, which caused Montgomery's brown water. Washington Post, June 17, 2015. Accessed 07-26-2015 at http://www.washingtonpost.com/local/montgomery-residents-complain-about-brown-tap-water/2015/06/17/d7910098-146c-11e5-9518-f9e0a8959f32_story.html
38. Williams, D.D.; Williams, N.E.; and Yong Cao. (1990), Road salt contamination of groundwater is a major metropolitan area, and development of a biological index to monitor its impact. *Water Research*, 34(1), 127-138 .
39. Penton, K. (2014). What you need to know about Brick's Water Contamination. Accessed June 26, 2015 at <http://www.app.com/story/news/investigations/watchdog/government/2014/11/19/lead-bricks-drinking-water/19298753/>.
40. Furlow, J.; Scheraga, J.D.; Freed, R.; and K. Rock. The vulnerability of public water systems to sea level rise. In *Proceedings of the Coastal Water Resource Conference*, John R. Lesnik (editor), American Water Resources Association, Middleburg, Virginia, TPS-02-1, 2002, 31-36.
41. Edwards, M.; Abhijeet, D. (2004), Role of chlorine and chloramine in corrosion of lead-bearing plumbing materials. *Journal American Water Works Association*. V. 96, No. 10 69-81.
42. Del Toral, M.; Porter, A.; and Schock, M. (2013). Detection and Evaluation of Elevated Lead Release from Service Lines: A Field Study. *Environmental Science & Technology*, 47 (16), 9300-9307
43. Gabler, E. August 5, 2011. High lead levels found in Chicago water. Accessed 7-26-2015 at <http://www.chicagotribune.com/lifestyles/health/ct-met-lead-in-water-20110805-story.html>.
44. Smith, L. July 13, 2015. Leaked internal memo shows federal regulator's concerns about lead in Flint's water. Accessed 7-28-2015 at <http://michiganradio.org/post/leaked-internal-memo-shows-federal-regulator-s-concerns-about-lead-flint-s-water#stream/0>

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, September 15, 2015 1:17 PM
To: reynolds@mottchc.org
Cc: Peeler, Nancy (DCH); Lishinski, Karen (DCH)
Subject: Lead graphs
Attachments: Flint Testing and EBLs.pdf

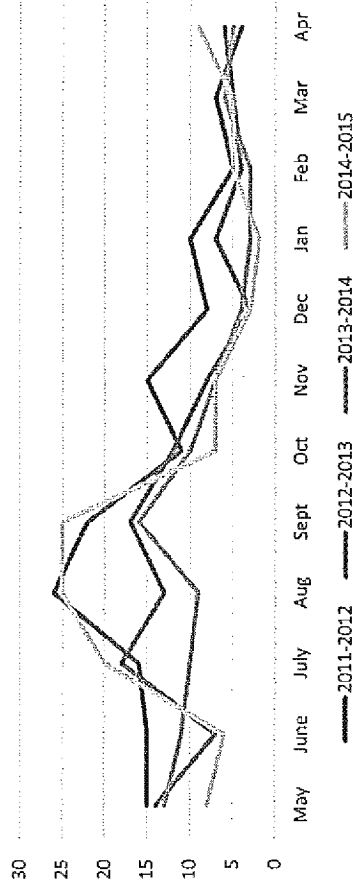
Dr. Reynolds,

Per your conversation with Nancy Peeler, please see attached. Let me know if you have any questions about the data.

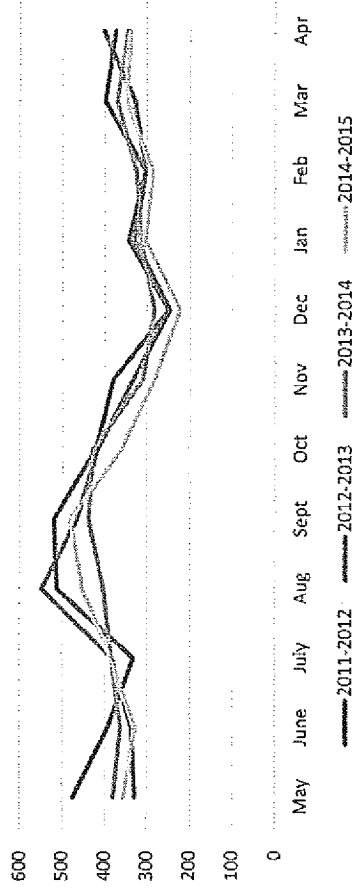
Thanks,
Bob Scott

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

City of Flint, Children less than 16 years of age
with First-Time Elevated Blood Lead Levels



City of Flint, Children less than 16 years of age
Tested for Lead Poisoning



	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2011-2012	15	15	16	26	22	11	15	8	10	5	7	4
2012-2013	14	7	18	13	17	12	8	3	7	4	5	6
2013-2014	13	11	10	9	16	10	7	4	3	3	6	5
2014-2015	8	6	20	25	25	7	7	3	2	5	5	9

	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2011-2012	474	393	332	513	520	420	379	249	343	303	399	375
2012-2013	328	338	383	550	464	417	332	246	328	303	328	402
2013-2014	380	363	385	404	438	427	310	283	313	325	371	346
2014-2015	356	329	386	452	480	361	283	224	305	287	348	339

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 3:28 PM
To: CDC/ONDIEH/NCEH (kfc2@cdc.gov)
Cc: Peeler, Nancy (DCH)
Subject: FW: Flint water study
Attachments: Rapid Proposal Final.pdf

Kimball,

Nancy asked me to forward this to you (please see attached).

Bob

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: Friday, September 11, 2015 1:09 PM
To: Peeler, Nancy (DCH) <PeelerN@michigan.gov>; 'Lishinski Karen (LishinskiK@michigan.gov)' <LishinskiK@michigan.gov>; Priem, Wesley F. (DCH) <priemw@michigan.gov>
Subject: Flint water study

Nancy, Karen and Wes,

I'm passing this along as follow-up to our previous attention to the Flint water changeover situation. The attached was submitted to me along with a request for de-identified data, which should be no problem.

When you have a few minutes you might want to take a look at it. Sounds like there might be more to this than what we learned previously. Yikes!

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 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@monttch.org email along with hey52@ gmail so I can access from anywhere

--

Lawrence Reynolds

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Wednesday, September 16, 2015 10:50 AM
To: Lawrence Reynolds; Mona Hanna-Attisha; Laura Carravallah; Dr. Lawrence Reynolds, M.D.
Cc: Peeler, Nancy (DCH)
Subject: RE: Lead level data

The CDC's and Michigan's "reference level" for blood lead is 5 ug/dL—with the understanding that there is no safe level of lead.

From: Lawrence Reynolds [mailto:lrey52@gmail.com]
Sent: Wednesday, September 16, 2015 10:35 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: Re: Lead level data

Ps- Is 5 or 10 the cut off lead ?

On Wed, Sep 16, 2015 at 10:30 AM, Lawrence Reynolds <lrey52@gmail.com> wrote:

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 .

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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

--
 Lawrence Reynolds

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Wednesday, September 23, 2015 10:53 AM
To: Mona Hanna-Attisha
Cc: Lawrence Reynolds; Peeler, Nancy (DCH)
Subject: RE: IRBNet Board Action
Attachments: DCH-1294 Data Use and Non-Disclosure Agreement 5-2015.doc

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: Scott, Robert L. (DCH)
Sent: Wednesday, September 23, 2015 10:57 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

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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

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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

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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

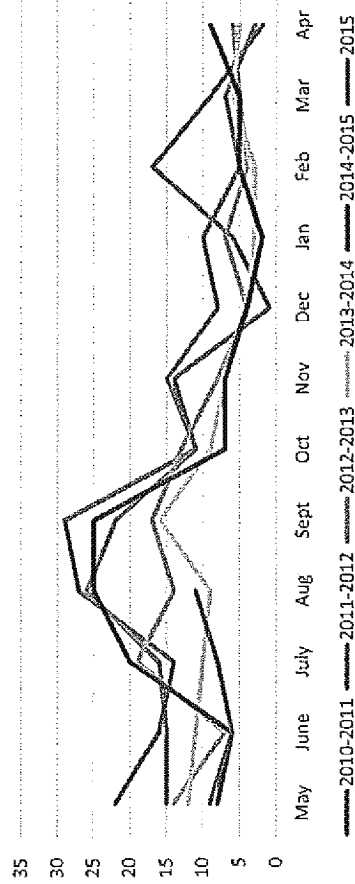
www.irbnet.org

Peeler, Nancy (DHHS)

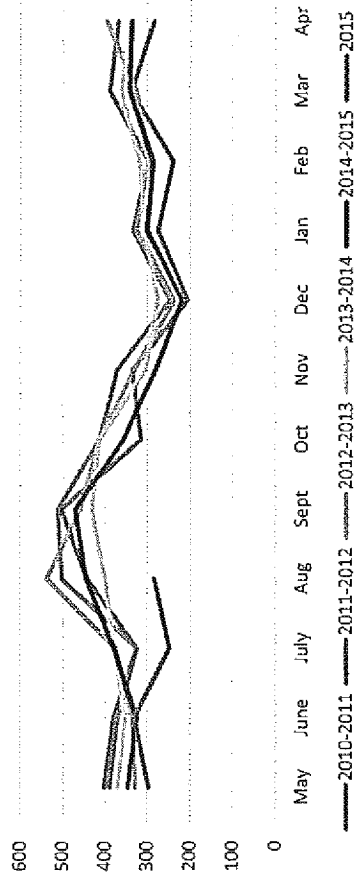
From: Scott, Robert L. (DCH)
Sent: Wednesday, September 23, 2015 4:41 PM
To: Peeler, Nancy (DCH)
Subject: pdf version
Attachments: Flint Testing and EBLLs_updated 092315.pdf

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

City of Flint, Children less than 16 years of age
with First-Time Elevated Blood Lead Levels



City of Flint, Children less than 16 years of age
Tested for Lead Poisoning



	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2010-2011	22	16	14	27	29	11	14	1	6	17	9	2
2011-2012	15	15	16	26	22	11	15	8	10	5	7	3
2012-2013	14	7	19	14	17	13	8	4	7	4	5	6
2013-2014	12	11	10	9	16	9	7	4	3	3	6	5
2014-2015	8	6	20	25	25	7	7	4	2	5	5	9
2015	9	6	8	11								

	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2010-2011	402	379	325	442	504	315	335	206	276	240	338	285
2011-2012	390	370	324	503	512	413	372	248	333	298	389	370
2012-2013	328	335	376	540	458	416	331	237	325	298	325	397
2013-2014	371	353	378	401	432	414	305	277	304	319	363	339
2014-2015	346	324	379	445	471	357	281	219	301	287	342	337
2015	297	330	249	284								

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Wednesday, September 23, 2015 4:48 PM
To: Peeler, Nancy (DCH)
Subject: pdf with notes
Attachments: Flint Testing and EBLLs_updated 092315_with notes.pdf

We can easily modify those notes if you want them to read differently.

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: Thursday, September 24, 2015 8:09 AM
To: Peeler, Nancy (DCH)
Subject: RE: Flint

Nancy,

Dr. Hanna-Attisha poked me again this morning about getting the updated charts. Can I send her what I gave you late yesterday, or do you want me to hold off?

Bob

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

From: Peeler, Nancy (DCH)
Sent: Wednesday, September 23, 2015 9:48 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: Flint

Based on questions coming through, I do think we need to run our Flint charts for the same population group that the Flint docs ran (as close as we can approximate the sample) but I'd look at it across the 5 years again.

Depending on what our charts show, we may want to consider having Epi help us run an analysis more like the docs ran - but let's look at the revised charts as a starting point.

Sent from my iPad

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 11:45 AM
To: Peeler, Nancy (DCH)
Subject: RE: what % of the sample we used for our charts were 0-5, vs. 6-16 year olds?

I just checked, about 10% of our "<16" were 6-16 year olds. That's been pretty consistent over the years, in all areas.

Yes, I'll be happy to join the call.

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

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

From: Peeler, Nancy (DCH)
Sent: Thursday, September 24, 2015 11:43 AM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: what % of the sample we used for our charts were 0-5, vs. 6-16 year olds?

And, do you want to join this next call? If so, I can add you in from my phone, not sure when they will call.

Sent from my iPad

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 11:50 AM
To: Peeler, Nancy (DCH)
Subject: RE: what % of the sample we used for our charts were 0-5, vs. 6-16 year olds?

Not sure what you mean.

I'll start running our data along the lines of Hurley's--children 0-5, the same zip codes they used. I'll also try to reproduce their results with the Hurley records, etc.

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

From: Peeler, Nancy (DCH)
Sent: Thursday, September 24, 2015 11:46 AM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: Re: what % of the sample we used for our charts were 0-5, vs. 6-16 year olds?

What is the next call?

Sent from my iPad

> On Sep 24, 2015, at 11:42 AM, Peeler, Nancy (DCH) <PeelerN@michigan.gov> wrote:
>
> And, do you want to join this next call? If so, I can add you in from my phone, not sure when they will call.
>
> Sent from my iPad

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 2:09 PM
To: Eisner, Jennifer (DCH)
Cc: Peeler, Nancy (DCH); Lounds, Elizabeth (DCH)
Subject: RE: blood lead levels for children by ZIP
Attachments: CLPPP 2013 Data Report.pdf

Jennifer,

Here is the 2013 data report on Lead in Michigan, the most recent we have with data by zip code.

From: Eisner, Jennifer (DCH)
Sent: Thursday, September 24, 2015 2:05 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: FW: blood lead levels for children by ZIP
Importance: High

Hi Bob:

Can you please assist with this request for more recent blood lead levels for children by ZIP (or statewide – whatever we have) after 2012?

Thank you,
 Jennifer

Jennifer Eisner
 (Formerly Jennifer Smith)
 Public Information Officer
 Michigan Department of Health and Human Services
 517-241-2112

From: Eisner, Jennifer (DCH)
Sent: Thursday, September 24, 2015 1:15 PM
To: Peeler, Nancy (DCH) <PeelerN@michigan.gov>; Lounds, Elizabeth (DCH) <LoundsE@michigan.gov>
Subject: FW: blood lead levels for children by ZIP
Importance: High

Hi Nancy:

Do we have more recent data than the link below? Please advise – thank you! Deadline asap.

Thanks!
 Jennifer

From: Tanner, Kristi [<mailto:ktanner@freepress.com>]
Sent: Thursday, September 24, 2015 11:17 AM
To: Eisner, Jennifer (DCH) <EisnerJ@michigan.gov>

Cc: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>

Subject: blood lead levels for children by ZIP

I found this report with ZIP data online that lists info for 2012.

Do you have the most recent complete listing of the % and number of children with elevated blood lead levels by ZIP?

Thanks!

http://www.michigan.gov/documents/mich/2012AnnualDataReportOnBloodLeadLevels_419508_7.pdf

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 2:50 PM
To: Peeler, Nancy (DCH)
Subject: flint lead powerpoint
Attachments: BLLs in Flint.pptx

Nancy,

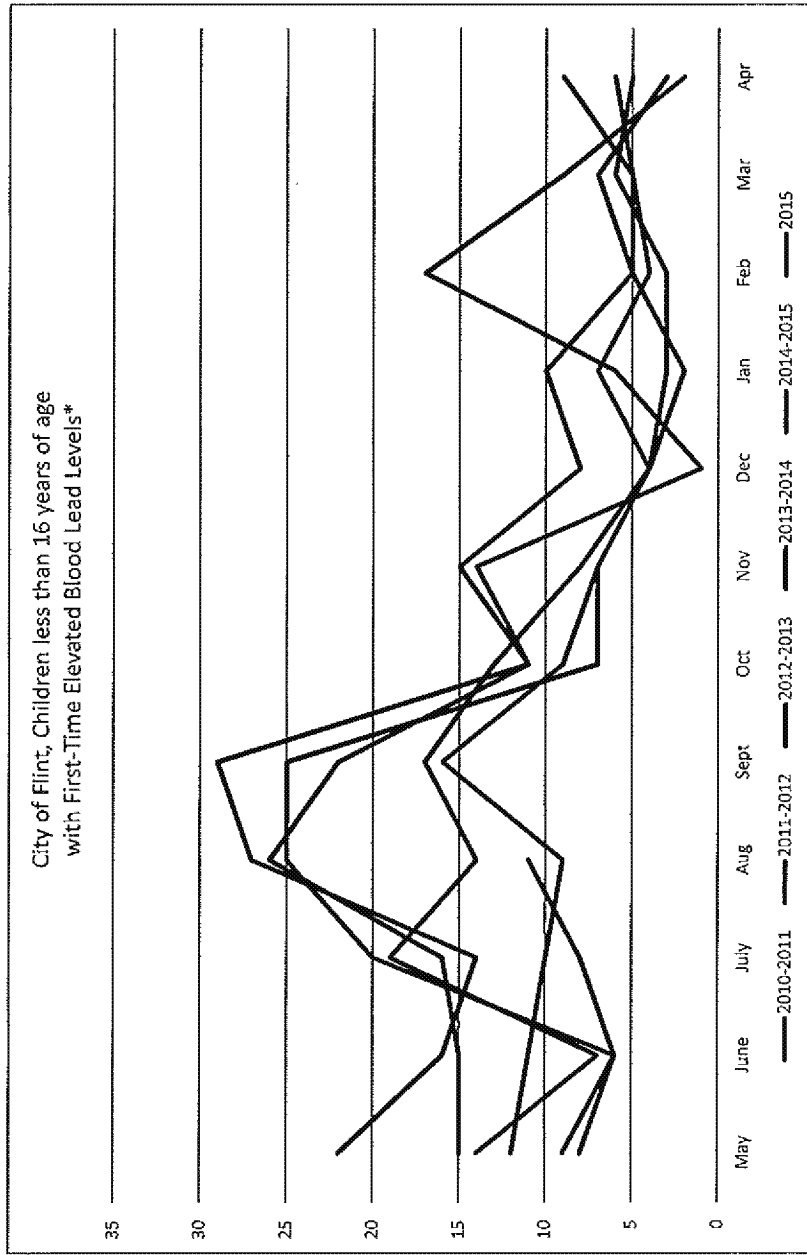
Please see attached. If for some reason you can't read/open it, let me know and I'll try it as a PDF.

Bob

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

Blood Lead Testing of Children in Flint, Before and After the Change in Flint's Water

- The change in Flint's water source occurred in April 2014. MDHHS looked at children's blood lead levels (BLL) before and after this event.
- The dark blue line (May 2014 – April 2015) and the green line (May-August 2015) reflect children's blood lead tests after the change. All other lines reflect tests before the change.
- An increase in childhood lead poisoning in summer (July, August, September) is typical throughout Michigan every year.
- While there is a dramatic difference between the numbers of elevated BLL in the summer before and after the event, a wider look that includes data back to 2010 shows that the year BEFORE the event (the yellow line) was more of an anomaly than the year after (the dark blue line).



*This graph includes:

Children whose address is listed as "Flint"—may not conform exactly to Flint city limits

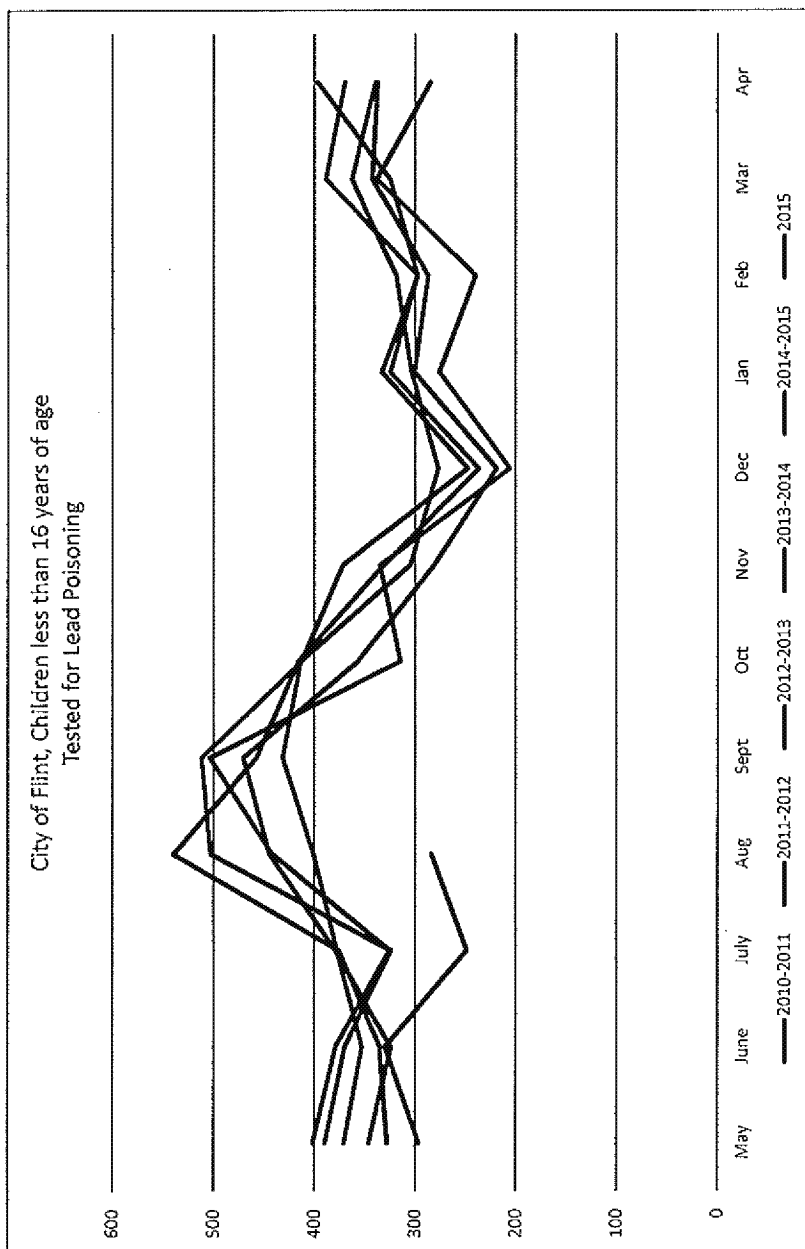
Children less than 16 years of age at time of test

Only first-time blood lead levels ≥ 5 ug/dL

All first-time elevated levels, regardless of sample type (venous, capillary or unknown)

Blood Lead Testing of Children in Flint, Before and After the Change in Flint's Water

- Blood lead testing (regardless of elevated levels) also tends to rise during late summer (August, September, October).
- This graph shows that testing in Flint has remained fairly steady over the last five years, except for a recent decline (May – August 2015).



*This graph includes:

Children whose address is listed as "Flint"---may not conform exactly to Flint city limits

Children less than 16 years of age at time of test

The number of children tested within each month.

Some children are tested more than once, and may be included in more than one month or year.

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 3:15 PM
To: Peeler, Nancy (DCH)
Subject: RE: flint lead powerpoint

Yes to both, will do & copy you, thanks.

From: Peeler, Nancy (DCH)
Sent: Thursday, September 24, 2015 3:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: Re: flint lead powerpoint

Only thought - should we way that if results were being driven by the water supply, we would expect the rate to remain at a higher rate?

Also, I forgot this earlier, probably too in the weeds - Larry Reynolds kept mentioning MCIR data - I don't think they know what our data source is that we use. Should we add any kind of a talking point that says all data included in this analysis is reported directly from labs to MDHHS, in accordance with state law?

If you think it worth adding those, go ahead, and send on to Jennifer. Thanks!

Sent from my iPad

On Sep 24, 2015, at 2:49 PM, Scott, Robert L. (DCH) <ScottR9@michigan.gov> wrote:

Nancy,

Please see attached. If for some reason you can't read/open it, let me know and I'll try it as a PDF.

Bob

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

<BLLs in Flint.pptx>

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 3:27 PM
To: Eisner, Jennifer (DCH)
Cc: Minicuci, Angela (DCH); Peeler, Nancy (DCH)
Subject: Flint lead powerpoint slides
Attachments: BLLs in Flint v2.pptx

Jennifer,

Nancy asked me to put this together, in case it's helpful. Please see attached.

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: Thursday, September 24, 2015 3:31 PM
To: Eisner, Jennifer (DCH)
Cc: Minicuci, Angela (DCH); Peeler, Nancy (DCH)
Subject: RE: Flint lead powerpoint slides

OK with me if it's OK with Nancy.

From: Eisner, Jennifer (DCH)
Sent: Thursday, September 24, 2015 3:29 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>; Peeler, Nancy (DCH) <PeelerN@michigan.gov>
Subject: RE: Flint lead powerpoint slides

Great, thanks Bob – can we make this available to the public?

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 3:27 PM
To: Eisner, Jennifer (DCH) <EisnerJ@michigan.gov>
Cc: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>; Peeler, Nancy (DCH) <PeelerN@michigan.gov>
Subject: Flint lead powerpoint slides

Jennifer,

Nancy asked me to put this together, in case it's helpful. Please see attached.

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: Thursday, September 24, 2015 3:45 PM
To: Peeler, Nancy (DCH)
Subject: one more document, attempt to recreate Hurley
Attachments: Attempt to replicate Hurley.xlsx

Nancy,

Thought I'd pester you one more time. I'm sure this one is not for the public. It's my attempt to recreate Hurley #s. I included EBL @ 5 & 6 just for comparison, but also looked at Venous-only vs. All types. I used children 0-5 and zip codes 48501-48507 just as Hurley did. I found a difference between the two years, but not as much difference as they did. For some reason I found more children tested than they did.

Let me know if you think it's worth pursuing any farther.

Thanks,
Bob

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

Children Tested for Blood Lead Before and After the Change in Flint's Water Supply

Hurley tests only
(Provider ID = 00000252)

Children Tested	(Hurley analysis) Children	Children with elevated blood lead levels				All (V, C, unknown)			
		Venous only							
	Tested	Pct >= 6	BLL >= 5	Pct >= 5	BLL >= 6	Pct >= 6	BLL >= 5	Pct >= 5	BLL >= 6
January 1 - September 15, 2013	1177	906	2.1	24	2.0	8	41	3.5	19
January 1 - September 15, 2015*	966	840	4.0	29	3.0	21	39	4	28

All Providers

Children Tested	Children with elevated blood lead levels				All (V, C, unknown)			
	Venous only							
	BLL >= 5	Pct >= 5	BLL >= 6	Pct >= 6	BLL >= 5	Pct >= 5	BLL >= 6	Pct >= 6
January 1 - September 15, 2013	2380	33	2.8	16	86	7.3	44	3.7
January 1 - September 15, 2015*	1928	40	4.1	28	80	8.3	54	5.6

Notes:

Children 0 - 5 years of age
Children living in zip codes 48501 -48507

Source: MDHHS Data Warehouse
September 24, 2015

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Thursday, September 24, 2015 5:05 PM
To: Minicuci, Angela (DCH)
Cc: Peeler, Nancy (DCH)
Subject: flint lead by year
Attachments: Flint lead testing and ebl by year.xlsx

Angela,

Per your request, please see attached.

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: Friday, September 25, 2015 9:35 AM
To: Minicuci, Angela (DCH); Eisner, Jennifer (DCH)
Cc: Peeler, Nancy (DCH)
Subject: question on email response regarding Flint blood lead data
Attachments: Flint Testing and EBLLs_updated 092315_with notes.pdf; HIPAA Waiver Request Template.doc; DCH-1277 IRB Initial Review Application.doc

Angela or Jennifer,

Please see Dr. Edwards email below, and my draft response to him. I'm not very happy with him right now, but tried to respond appropriately. Given the sensitive nature of the situation, I'm checking with you first. Nancy is on annual leave, but I've CC'd her here.

Is it OK to send this? Please feel free to make changes as appropriate. I'm also asking if it's OK now to share the attached PDF with Dr. Edwards and Dr. Hanna-Attisha.

Thanks,
 Bob

Marc,

As you well know, the data you and Dr. Hanna-Attisha are requesting are derived from personal health data, which of course is confidential. There are state and federal laws governing what can be shared, and how, with researchers or the public. In addition, my Department has policies on how to determine what can be shared.

I worked with you earlier this month to get data to you relatively quickly, but did not manage to complete the process before I went on annual leave for several days. I neglected to inform you that I'd be away, and I apologize for not informing you. Unfortunately we are a very small program, and there's no one else here to process your request—or Dr. Hanna-Attisha's.

Since I returned on Wednesday, my time has been largely taken up with my Department's response to the current situation in Flint. I did manage to correspond to Dr. Hanna-Attisha, and provided her with the forms she'll need for her request. I hope to submit her request to our Legal office and to our IRB contact today.

Sorry I haven't responded to your email from Monday—as I mentioned above, I was away, and then have been juggling many tasks since I returned. I think you'll be able to get approval for data with zip code identified. I'll edit your data use agreement accordingly, and will adjust it to say "limited data set" instead of "de-identified." I'll re-submit your DUA to Legal today. You will need to submit an MDHHS IRB review application (attached) because this is considered research. You should also submit a "HIPAA Waiver Request" (attached). (I wasn't aware of that when we talked earlier this month.) I don't know whether you'll need to go through an IRB review with your institution.

I've also attached a PDF that includes the numbers behind the graphs you referred to, and I'm CC'ing Dr. Hanna-Attisha so that she has it as well.

Bob

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

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Thursday, September 24, 2015 8:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Dear Robert,

I just spoke to this young researcher at Hurley, and apparently, she has been unable to get access to the state blood lead records.

I have to say, it is very disturbing that the state keeps issuing these blood lead reports and statements in their press releases, and refuses to share the data backing them up with outside researchers.

Even worse, state reps are running around claiming that these reports are proof that Flint water is safe to drink.

Can you tell me why it is so difficult to get this data, and why your agency is raising so many obstacles to sharing it with everyone who asks? I note that I have been asking to see your data since MDEQ first sent it to reporters back in August, and I count 10 e-mails that I sent responding to all your questions. As of yet, you have given me nothing in response. Yet you have been sending reporters one report after another. It seems your agency is more interested in public relations than sound science.

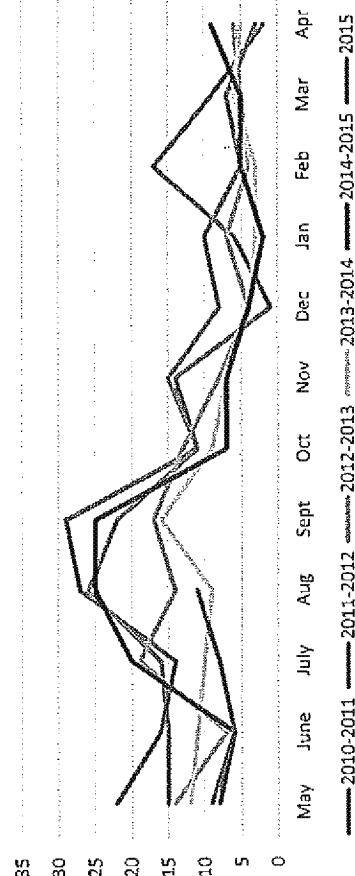
In the meantime, can I at least be given the numbers of EBL cases and number of tests each month, that are the basis for the latest graph your agency is sending to the press...or is that top secret as well?

Marc

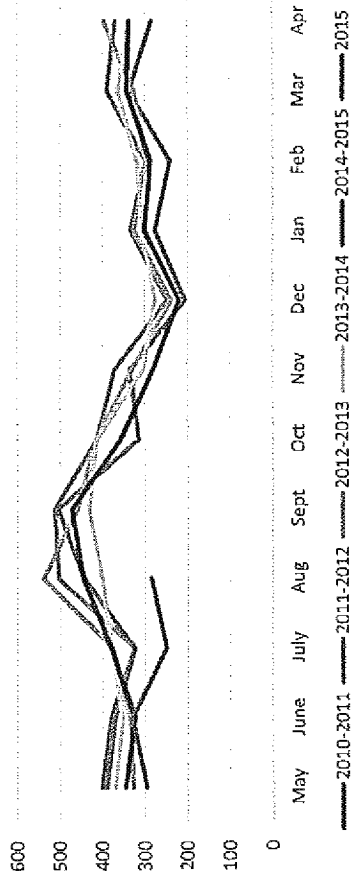
From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.

City of Flint, Children less than 16 years of age
with First-Time Elevated Blood Lead Levels*



City of Flint, Children less than 16 years of age
Tested for Lead Poisoning



	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
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2011-2012	15	15	16	26	22	11	15	8	10	5	7	3
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2013-2014	12	11	10	9	16	9	7	4	3	3	6	5
2014-2015	8	6	20	25	25	7	7	4	2	5	5	9
2015	9	6	8	11								

	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2010-2011	402	379	325	442	504	315	335	206	276	240	338	285
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2012-2013	328	335	376	540	458	416	331	237	325	298	325	397
2013-2014	371	353	378	401	432	414	305	277	304	319	363	339
2014-2015	346	324	379	445	471	357	281	219	301	287	342	337
2015	297	330	249	284								

*Children whose address is listed as "Flint"--may not conform exactly to Flint city limits

Less than 16 years of age at time of test

Includes only first-time blood lead levels ≥ 5 ug/dL

Includes sample type of venous, capillary or unknown

September 23, 2015

Source: MDHHS Data Warehouse, Lead Specimen table

Study Title: (please enter study title here)

Responsible Department Employee: (please enter Responsible Department Employee's name here)

Primary Investigator: (please enter Primary Investigator's name here)

Research Staff Requiring Access to Protected Health Information (PHI):
(please list all staff who will access PHI here)

Name(s) of Covered Entity(ies) and Location(s) Where PHI Will Be Reviewed:
(please list entities and associated addresses here)

PHI Required and Intended Use:
(please describe PHI here)

Does the use or disclosure of the PHI involve more than minimal risk to the privacy of the potential subjects? (please select one answer) ☐ YES ☐ NO
(please explain your response here)

Describe your plan to destroy identifiers at the earliest opportunity consistent with conducting the research. (All identifier links must be destroyed for minimal risk research. For other research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. If retention of identifiers is required, explain the reason and indicate that the identifiers will be stored and retained.)

(please describe destruction or required retention of identifiers here)

Describe your plan to adequately protect the identifiers from improper use and disclosure (Check all that apply and explain other protective measures you will use):

- ☐ Names and other direct identifiers of individuals will be removed at the earliest possible time if consistent with research design
- ☐ Protected health information (PHI) will be kept in locked storage when not in use
- ☐ Records of research subjects or potential subjects will be kept separate from other patient records
- ☐ Access to records will be restricted to those persons directly involved in the research
- ☐ Records of individuals not selected to participate in research will be destroyed as soon as possible
- ☐ If researcher discloses PHI to a third party (e.g. a research sponsor, data analyst, centralized database, etc.) researcher has received written assurances that the third party will maintain confidentiality of the PHI

(please describe additional protections to be employed here)

Describe why the study could not practicably be conducted without access to and use of the protected health information (PHI) requested:

(please provide a detailed description here)

Describe why the study could not practicably be conducted without this Waiver of Authorization:

(please provide a detailed description here)

Statement of the Primary Investigator:

I affirm that:

- *The requested access, use or disclosure of PHI is necessary for the purposes of the proposed research;*
- *The requested access, use or disclosure of PHI is solely for the purpose for which waiver is being requested;*
- *The waiver of authorization will not adversely affect the welfare or privacy rights of the research subjects;*
- *The benefits of research outweigh the risks to the privacy rights of the research subjects;*
- *The requested information constitutes the minimum necessary data to accomplish the goals of the research; and,*
- *The protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule.*

Primary Investigator's Signature

Date

The Michigan Department of Community Health
Institutional Review Board for the Protection of Human Research Subjects
 Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
 E-mail: MDCH-IRB@michigan.gov Phone: (517) 241-1928 Fax: (517) 241-1200

MDCH IRB INITIAL REVIEW APPLICATION

SECTION 1 – PROJECT IDENTIFICATION (*REQUIRED*)

1.1 **Project Title:**

Note: The project title provided above should appear on each document submitted to the MDCH IRB for this study review.

1.2

Responsible MDCH Employee Name:	
Phone:	
E-mail:	
ID Mail Address:	

Note: The Responsible MDCH Employee must be a Civil Service employee of MDCH and should be the employee most responsible for the Department's role in this project. To serve as the responsible MDCH employee you must have completed CITI human research protections training within the past 3 years.

1.3 **Responsible MDCH Employee's Signature:**

Note: If this document is submitted from the e-mail address of the Responsible MDCH Employee, a hard copy with signature is not required.

1.4

Responsible MDCH Employee's Administration:	
Bureau or Office:	
Bureau or Office Director/Supervisor:	
E-mail for this supervisory contact:	
ID Mail Address for this supervisory contact:	

The Bureau Director (or equivalent supervisor) listed above will receive copies of IRB determinations.

1.5

Principle Investigator:	
Organization:	
Phone:	
E-mail:	

Note: Contact information is requested for use if the Responsible MDCH Employee is not available.

1.6

Is this project federally funded?	☐ Yes ☐ No
If "Yes", specify the federal agency:	

1.7 **Non-Federal funding source(s) if applicable:**

1.8

Is this project subject to FDA regulations? ☐ Yes ☐ No		
If "Yes", please specify below which FDA-regulated test articles will be used:		
☐ No test article used		
☐ Drug or biologic used	IND#:	Trial Phase:
☐ Device used	IND#:	Risk Level: Choose One

1.9

What date do you plan to begin this project?	
What date do you plan to complete this project?	

1.11

Will another organization's IRB review this project?	☐ Yes ☐ No
If "Yes", please list the organization(s) here:	

1.12 **Describe any conflicts of interest that could be perceived to compromise the integrity of the project:**

SECTION 2 – PROJECT SUMMARY (REQUIRED)

2.1 Provide a summary of about 300 words (or less) in lay terms describing the project. This should not be as detailed as a study protocol (which you can attach separately). Please describe: the purpose of the project, how human subjects will participate, how subjects' data or biological specimens will be handled, how records will be maintained securely, and any follow up with subjects at completion.

2.2 Federal regulations define research as: "...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Please indicate whether this project is research, or why you feel it may not include research:

☐ This project is research.

☐ This project may not be research for the following reason(s):

2.3 Indicate in what way human subjects might be involved in this project (check all that apply):

☐ Data about the subjects and/or biological specimens that have already been collected will be retrospectively analyzed.	SECTIONS 1-8 ARE REQUIRED
☐ Data about the subjects and/or biological specimens that will be prospectively collected for non-research purposes will be analyzed.	SECTION 1-8 ARE REQUIRED
☐ Human subjects will be surveyed, interviewed, or participate in focus groups.	SECTIONS 1-7, 9 & 10 ARE REQUIRED
☐ Human subjects will undergo experimental treatment or intervention.	SECTIONS 1-7, 9 & 11 ARE REQUIRED
☐ Non-invasive measurements or tests will be performed on human subjects.	SECTIONS 1-7, 9 & 12 ARE REQUIRED
☐ Biological specimens (blood, saliva, tissue, etc.) will be collected from human subjects.	SECTIONS 1-7, 9 & 13 ARE REQUIRED
☐ Genetic analysis will be performed on biological samples from human subjects.	SECTIONS 1-7, 9 & 14 ARE REQUIRED
☐ Human subjects are not involved because the investigator will not be obtaining information about individuals through intervention or interaction, and the investigator will not otherwise be obtaining private, identifiable information about living individuals.	STOP AND SUBMIT ONLY WHAT IS COMPLETED THUS FAR TO THE IRB
☐ Other, please specify:	

Note: Your selection(s) above may indicate additional sections of the IRB application that you are required to complete. Please complete these additional sections before submitting the application to the IRB.

2.4 Certain research involving human subjects may be eligible for approval under an exemption as described in the federal regulations at 46.101(b): <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101>. If you feel your research is eligible for exemption, please list the category (1-6) below. Leave this blank if not applicable. You may also find this tool helpful: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

Exemption Category 46.101(b) _____

2.8 Indicate below what other documents are included with this submission:

☐ Study protocol

☐ Informed consent and assent (as applicable) instrument(s)

☐ Investigator's brochure

☐ Subject recruitment materials

☐ Survey instruments

☐ HIPAA-Compliant request for waiver of authorization

SECTION 3 – INFORMED CONSENT PROCESS

The Belmont principles dictate that potential study subjects should understand the research project: the procedures to be followed, the risks and benefits associated with participation, and alternatives to participation, prior to voluntarily consenting to participate in research. It is the obligation of the investigator to implement a process that facilitates such understanding, allows participants an opportunity to consent or to not consent to participation, and ensures the consent of participants is maintained throughout participation in the study. Obtaining and documenting informed consent is a process meant to aid in protecting human subjects of research. Obtaining a participant's signature is not intended to be a mechanism to protect the investigator or institution. For more information please see: "Guidelines for Informed Consent" located on the MDCH IRB website: www.michigan.gov/irb.

3.1 Indicate how you intend to document having obtained informed consent and/or assent from participants in this project, or indicate that you do not intend to document having obtained informed consent (select all that apply):

☐ Informed consent of the study subjects will not be documented. (complete Section 3.2)

☐ A comprehensive written document will be signed by the subject or a legally authorized representative. (skip to section 3.3)

☐ A short written document that satisfies the criteria under 46.117(b)(2) (described here: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>) will be signed by the subject or a legally authorized representative. (skip to section 3.3)

☐ A document indicating assent/willingness to participate will be signed by child participants. (skip to section 3.3)

3.2 Indicate below the rationale for not documenting that informed consent of participants has been obtained:

☐ As indicated in 2.2 above, I do not believe this activity involves research. (skip to section 4)

☐ As indicated in 2.4 above, I believe this research is eligible for exemption. (skip to section 4)

☐ I am obtaining informed consent from study participants, but do not wish to document having obtained informed consent as allowable under 46.117(c) (described here: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>) (skip to and complete section 3.4)

☐ I am requesting a waiver of the requirement for obtaining participant's informed consent as allowable under 46.116(c) or (d) (described here: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>) (skip to and complete Section 3.5)

3.3 Describe the process of obtaining informed consent (and if applicable, assent) from study participants, and ensuring the consent of participants is maintained throughout the duration of their participation in the study.

Note: After completing section 3.3 you can proceed to section 4 of the application.

3.4 Describe below the process you intend to utilize to obtain informed consent from study participants. Conclude this section by describing how your proposal meets the requirements for a waiver of documenting informed consent as described under 46.117(c).

Note: After completing section 3.4 you can proceed to section 4 of the application.

3.5

Document in A or B below how your proposal meets the requirements for a waiver of the requirement that informed consent be obtained from study participants.	
A.	Is this a research or demonstration project conducted by or subject to approval of state or local government officials? ☐ Yes ☐ No
	If Yes, is it designed to study, evaluate, or otherwise examine:
	☐ public benefit or service programs
	☐ procedures for obtaining benefits or services under those programs
	☐ possible changes in or alternatives to those programs or procedures
	☐ possible changes in methods or levels of payment for benefits or services under those programs
	Is it the case that the research cannot practicably be carried out without a waiver of the requirement for obtaining informed consent? If Yes, please explain below: ☐ Yes ☐ No
OR	
B.	Does this research involve no more than minimal risk to subjects? ☐ Yes ☐ No
	Would waiving the requirement for informed consent adversely affect the rights and welfare of the subjects? ☐ Yes ☐ No
	Whenever appropriate, will subject be provided with additional pertinent information after participation? ☐ Yes ☐ No
	Is it the case that the research cannot practicably be carried out without a waiver of the requirement for obtaining informed consent? If Yes, please explain below: ☐ Yes ☐ No

SECTION 4 – CHARACTERISTICS OF HUMAN SUBJECTS

4.1

Briefly describe the characteristics of the population from which you intend to draw participants and discuss why that population was chosen:

4.2

Detail the inclusion and exclusion criteria for project participants:

4.3

If applicable, please justify limitation of participants to a particular demographic group (age, gender, race, ethnicity, income, etc.):

4.4

Select any vulnerable populations that may be represented among research subjects. If vulnerable subjects are purposefully selected please provide justification for the inclusion of these vulnerable populations. If inclusion is possible, but incidental, please note that as well.

Category of vulnerable subjects:	Justification for inclusion:
☐ Children (age <18 years)	
☐ Mentally compromised persons or persons with decisional impairment	
☐ Women with reproductive potential	
☐ Pregnant or lactating women	
☐ Fetuses (<i>ex utero</i>)	
☐ <i>In-vitro</i> fertilization patients	
☐ Prisoners	

Note: With respect to the regulations at 45 CFR 46 part C, patients at the Center for Forensic Psychiatry are considered "Prisoners" and their participation should be indicated as such above.

4.5

Select from the list below any populations that could be subject to undue influence or coercion, and justify inclusion of these populations.

Category of subjects:	Justification for inclusion:
☐ Economically or Educationally Deprived	
☐ Patients of the investigator	
☐ Students of the investigator	

☐ Employees of the investigator

SECTION 5 – RISKS AND BENEFITS OF THE RESEARCH

- 5.1 Indicate how substantial you believe the risk of harm to participants is for this project:
- ☐ High risk
☐ Less than high risk, but greater than minimal risk
☐ Minimal risk
- Note: "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*
- 5.2 What direct risks could subjects face by participating in this project? What measures will be taken to minimize each risk?
- 5.3 If "Vulnerable populations" or populations susceptible to undue influence or coercion are among the research subjects, what additional measures will be taken to minimize risks that may affect them?
- 5.4 What indirect risks (if any) to the public or community could result from this research?
- 5.5 What potential direct benefits (if any) could this research provide the participating subjects?
- 5.6 What potential indirect benefits (if any) could this research provide the public or others?

SECTION 6 – RECORDS, PRIVACY & CONFIDENTIALITY

- 6.1 Will the project records themselves contain identifying information on human subjects (i.e. name, address, telephone number, e-mail address, etc.)?
- ☐ Yes ☐ No
- 6.2 Will the project records contain codes that can be linked back to the identity of human subjects?
- ☐ Yes ☐ No
- 6.3 If the information in the project records was revealed could it place the subjects (or others) at risk for criminal or civil liability? Or could it be damaging to an individual's financial standing, employability, or reputation?
- ☐ Yes ☐ No
- 6.4 Describe the measures you will implement to ensure the privacy (the right of an individual to control his or her own personal information) of project participants.
- 6.5 Describe the measures you will implement to ensure the confidentiality of subjects information once it is part of the research record?
- Note: Confidentiality in the use of data requires at a minimum: (a) not including personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to the research; (b) removing personal identifiers at the earliest stage of the research compatible with the study goals; (c) If personal identifiers must remain (e.g. to link with future data) these should be limited to codes that are not based on identifying information and they should be encrypted and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.*
- 6.6 If applicable, describe when and how subject identifiers will be destroyed:

SECTION 7 – COSTS AND COMPENSATION

7.1 Describe any costs a research subject might incur as a result of participating in this research including indirect costs such as billing to a patient's insurance:

7.2 Describe any plans to compensate research subjects:

7.3 If subjects will be compensated, how was the amount or type of compensation decided upon?

This concludes the portion of the application required for all new projects. The remaining sections are only required based on your responses to question 2.3 above, or at the guidance of IRB staff.

SECTION 8 – PROJECTS INVOLVING ONLY THE ANALYSIS OF DATA OR BIOLOGICAL SPECIMENS THAT ALREADY EXIST, OR WILL BE COLLECTED FOR NON-RESEARCH PURPOSES

8.1 Describe the type of data and/or biological specimens to be used in this project.

8.2 If data or biological samples currently exist, describe how and for what purpose they were originally collected. If data or samples do not exist but will be collected prospectively for non-research purposes, describe how and for what purpose they will be collected.

8.3 At the time of collection, are or were samples stored in a way that could reveal the identity of the person from whom they originated?

8.4 From how many human subjects will these data or specimens be acquired?

8.5 Describe how the investigator plans to gain access to these data and/or specimens?

8.6 Did or will the human subjects provide consent at the time of data or specimen collection allowing for subsequent use of the data or specimens in research?

☐ Yes ☐ No

8.7 Describe any access project staff have to information about the human subjects that is not essential to this project. Describe the measures in place to protect that information.

8.8 Could this project reveal information of direct benefit to the human subjects involved?

☐ Yes ☐ No

If "Yes", describe the plans to inform subjects of this information:

8.9 Could the project lead to the development of a commercial product that may bring financial benefit to the investigator and/or sponsor?

☐ Yes ☐ No

If "Yes", describe the plans to inform subjects of their rights:

8.10 Is there a signed Data Use Agreement or Material Transfer Agreement for this project?

☐ Yes ☐ No

If "Yes", include a copy with the application, if "No", justify why no such agreement is in place:

SECTION 9 – SUBJECT RECRUITMENT PROCEDURES

- 9.1 Describe how potential participants will be identified for recruitment (e.g. from an existing registry, convenience sampling, random digit dialing, etc.):
- 9.2 Describe from where (e.g. at home, in a clinic, etc.) the potential participants will be recruited?
- 9.3 Describe how (e.g. phone call, brochure, letter) potential participants will be recruited:
- 9.4 Print materials or transcripts of audible recruitment materials should be included in the IRB application for review (or should be approved for use by the IRB before implemented). Please list any recruitment materials included for review with this application:
- 9.5 If the project involves a topic that may have specific relevance to certain ethnic, racial, or other groups, what special measures will be taken to optimize recruitment of subjects from those groups?

SECTION 10 – INTERVIEWS, SURVEYS OR GROUP MEETINGS

- 10.1 Describe the methods (survey, interview, focus group, etc.) that will be used to collect information directly from human subjects:
- 10.2 How many sessions are proposed to collect this information, and how many sessions will each individual participant be required to attend? Also, what is the anticipated duration of each session?
- 10.3 Describe the information that will be collected through surveys, interviews, or focus groups:
- 10.4 Will the information that will be collected directly from participants include sensitive information such as substance use or illegal activities?
- 10.5 How will the privacy of the subjects be protected while collecting information about them?
- 10.6 Describe how the information collected during these procedures will be recorded:
- 10.7 Describe how any survey records will be labeled or identified to directly or indirectly link to the project participant.
- 10.8 Are surveys, questionnaires, and/or interview guides attached? ☐ Yes ☐ No

SECTION 11 – EXPERIMENTAL TREATMENTS OR PROCEDURES

- 11.1 Research in this category requires MDCH IRB approval of the study protocol. The protocol should describe the goals of the study, background information, specific aims, experimental design, statistical analysis of results, subject of the research, risks and benefits of treatment or procedures, and significance of outcomes. Indicate here you have read this paragraph and attached a protocol: ☐ Protocol attached.
- 11.2 Describe any treatments or procedures including tests and diagnostics that are done only for the purpose of the research (not as part of standard care).

SECTION 12 – NON-INVASIVE MEASUREMENTS OR TESTS

12.1 Describe the nature of the non-invasive tests and measurements which human subjects will undergo as part of this project:

12.2 Describe the measures taken to ensure participant privacy during these tests and measurements:

12.3 How often will these measurements or tests occur? How long does each session of tests or measurements take?

SECTION 13 – BLOOD AND OTHER BIOLOGICAL SPECIMENS TO BE TAKEN FROM SUBJECTS FOR THE PURPOSES OF THIS PROJECT

13.1 Describe how blood (venipuncture, finger stick, etc.) will be obtained for the purposes of this project? Indicate if not applicable.

13.2 State the number of times, the intervals, and the time-span over which blood will be collected? Indicate if not applicable.

13.3 What is the largest volume of blood to be taken from a subject during a single draw? Indicate if not applicable.

13.4 What is the total volume of blood to be taken from a subject during the entire project? Indicate if not applicable.

13.5 Describe what other biological specimens will be obtained for this project? Indicate if not applicable.

13.6 Describe how non-blood biological specimens will be obtained and stored for this project? Indicate if not applicable.

13.7 Will collection of biological specimens occur as part of the human subject's standard care?

☐ Yes ☐ No

If "No", please explain:

13.8 Describe the subject's right to financial benefit from use of his or her biological specimens for this project:

13.9 Describe the process for disposal of biological specimens, including all rights of the subject and obligations of the researcher, if there are plans to store the material for future use:

SECTION 14 – GENETIC ANALYSIS OF BIOLOGICAL SPECIMENS TO BE OBTAINED FROM RESEARCH SUBJECTS

Resources related to genetics research are available here: <http://www.genome.gov/Issues/>

- 14.1 Describe the biological specimens that will be used for genetic analysis:
- 14.2 Describe the nature of the genetic information that will be acquired:
- 14.3 What is the specific purpose of the genetic analysis?
- 14.4 Describe potential risk to the study subject or related family members from this genetic information:
- 14.5 Describe how genetic material will be kept confidential and secure:
- 14.6 Describe the process for providing genetic information to the subject (options to know or not know results, circumstances involving genetic abnormalities and parenthood, etc.):
- 14.7 Do you plan to offer genetic counseling to participants?
☐ Yes ☐ No
Please explain:
- 14.8 Describe the subject's right to financial benefit from use of his or her genetic material for this project:
- 14.9 Describe the process for disposal of genetic material, including all rights of the subject and obligations of the researcher, if there are plans to store the material for future use:

INSTRUCTIONS FOR SUBMITTING YOUR APPLICATION

1. Verify all required elements of the application are complete
2. Attach any materials study subjects will encounter as part of the project (recruitment materials, informed consent documents, survey instruments, etc.) as well as any protocol documents or data gathering tools used by the investigator.
3. Ensure approval by the Responsible MDCH Employee (*note: Responsible MDCH Employee's should perform a programmatic review to ensure MDCH involvement in the project is appropriate, and should serve as the first line in identifying and addressing human research protection issues that may be pertinent to the project*)
4. The Responsible MDCH Employee should indicate approval and submit the complete application by e-mailing all documents from his or her MDCH e-mail account to: MDCH-IRB@michigan.gov, or by signing the application and mailing all materials (ID mail or otherwise) to:
MDCH Institutional Review Board
Capitol View Building, 7th Floor
201 Townsend Street
Lansing, Michigan 48913

Completion of this application is required for IRB Review at MDCH when MDCH is the only organization involved in the project, or when MDCH has primary responsibility for the project. An abbreviated form of the application can be used if review will occur through another institution's IRB (see: MDCH IRB Abbreviated Initial Review Application) and if all materials submitted to the other institution's IRB are submitted to the MDCH IRB as well.

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

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 25, 2015 10:54 AM
To: Peeler, Nancy (DCH)
Subject: RE: question on email response regarding Flint blood lead data

I agree that his statements are inappropriate; they are plenty of things I'd LIKE to say in response, but won't.

I can make changes according to your comments below, thanks. Should I wait to hear from Angela? Wait a couple more hours?

From: Peeler, Nancy (DCH)
Sent: Friday, September 25, 2015 10:37 AM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: Re: question on email response regarding Flint blood lead data

I'm sitting in Zoe's quantum mechanics class, no clue what these differential equations are telling me, but I am stewing a bit about this situation. I want to say that you always do a great job, and are responsive to all data requests, and advocate to help researchers get whatever paperwork completed and turned in. That's why this feels so inappropriate to me - this isn't your fault, thus my earlier comment about apologizing less. And having said that, it probably wasn't a really helpful comment toward revising the response.

The email you received could be read as an intent to escalate and spin things, and I don't think you need to get caught up in that. A calm, fact-based response is very appropriate.

I think your first paragraph is good, but I would remove the last sentence, as I'm not sure what policies you are referencing beyond state and federal law -- and, I think the state and federal law carry enough weight that our departmental policies probably don't change much of anything about the process.

For paragraphs 2 and 3 I think I would just say state the facts, which is that both requests are in process in accordance with departmental policies - because they are. You really don't need to apologize for taking vacation, and I consider anybody's vacation time to be a normal part of doing business - none of us are expected to be at our desks every day, and there is no way to predict what might come up when we are planning to be away.

In your 4th paragraph, it looks like he is changing his data request? I appreciate your generosity in taking on responsibility to do his work for him (editing his paperwork) - your option, whether you want to do that, or request that he re-do it. I would outline the steps, clarify that you have confirmed the process which revealed the extra step, and let him know you'll watch for his response.

Finally, I might close with the piece about a small program, responsible for processing a high number of results every day or week (you sent me a number last week) in order to get them out to the professionals working directly with children and families, which IS the purpose and highest priority of our program.

I hope some of this is helpful and not too late - hope the rest of the day goes better. Thank you for all you do!

Sent from my iPad

On Sep 25, 2015, at 9:34 AM, Scott, Robert L. (DCH) <ScottR9@michigan.gov> wrote:

Angela or Jennifer,

Please see Dr. Edwards email below, and my draft response to him. I'm not very happy with him right now, but tried to respond appropriately. Given the sensitive nature of the situation, I'm checking with you first. Nancy is on annual leave, but I've CC'd her here.

Is it OK to send this? Please feel free to make changes as appropriate. I'm also asking if it's OK now to share the attached PDF with Dr. Edwards and Dr. Hanna-Attisha.

Thanks,
Bob

Marc,

As you well know, the data you and Dr. Hanna-

Attisha are requesting are derived from personal health data, which of course is confidential. There are state and federal laws governing what can be shared, and how, with researchers or the public. In addition, my Department has policies on how to determine what can be shared.

I worked with you earlier this month to get data to you relatively quickly, but did not manage to complete the process before I went on annual leave for several days. I neglected to inform you that I'd be away, and I apologize for not informing you. Unfortunately we are a very small program, and there's no one else here to process your request—or Dr. Hanna-Attisha's.

Since I returned on Wednesday, my time has been largely taken up with my Department's response to the current situation in Flint. I did manage to correspond to Dr. Hanna-Attisha, and provided her with the forms she'll need for her request. I hope to submit her request to our Legal office and to our IRB contact today.

Sorry I haven't responded to your email from Monday—as I mentioned above, I was away, and then have been juggling many tasks since I returned. I think you'll be able to get approval for data with zip code identified. I'll edit your data use agreement accordingly, and will adjust it to say "limited data set" instead of "de-identified." I'll re-submit your DUA to Legal today. You will need to submit an MDHHS IRB review application (attached) because this is considered research. You should also submit a "HIPAA Waiver Request" (attached). (I wasn't aware of that when we talked earlier this month.) I don't know whether you'll need to go through an IRB review with your institution.

I've also attached a PDF that includes the numbers behind the graphs you referred to, and I'm CC'ing Dr. Hanna-Attisha so that she has it as well.

Bob

Robert L. Scott

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

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Thursday, September 24, 2015 8:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Dear Robert,

I just spoke to this young researcher at Hurley, and apparently, she has been unable to get access to the state blood lead records.

I have to say, it is very disturbing that the state keeps issuing these blood lead reports and statements in their press releases, and refuses to share the data backing them up with outside researchers. Even worse, state reps are running around claiming that these reports are proof that Flint water is safe to drink.

Can you tell me why it is so difficult to get this data, and why your agency is raising so many obstacles to sharing it with everyone who asks? I note that I have been asking to see your data since MDEQ first sent it to reporters back in August, and I count 10 e-mails that I sent responding to all your questions. As of yet, you have given me nothing in response. Yet you have been sending reporters one report after another. It seems your agency is more interested in public relations than sound science.

In the meantime, can I at least be given the numbers of EBL cases and number of tests each month, that are the basis for the latest graph your agency is sending to the press...or is that top secret as well?

Marc

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.

<Flint Testing and EBLs_updated 092315_with notes.pdf>

<HIPAA Waiver Request Template.doc>

<DCH-1277 IRB Initial Review Application.doc>

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 25, 2015 12:44 PM
To: Marc Edwards
Cc: Mona Hanna-Attisha; Peeler, Nancy (DCH); Minicuci, Angela (DCH)
Subject: RE: Automatic reply: New DCH-1294, time-sensitive
Attachments: HIPAA Waiver Request Template.doc; Flint Testing and EBLs_updated 092315_with notes.pdf; DCH-1277 IRB Initial Review Application.doc

Marc,

As you well know, the data you and Dr. Hanna-Attisha have requested are derived from personal health data, which of course is confidential. There are state and federal laws governing what can be shared, and how, with researchers or the public.

I worked with you earlier this month to get data to you relatively quickly, but we did not manage to complete the process before I went on annual leave for several days. I neglected to inform you that I'd be away. I returned on Wednesday and corresponded that day with Dr. Hanna-Attisha, providing her with the forms she'll need for her request.

Regarding your email from Monday, I think you'll be able to get approval for data with zip code identified. I'll edit your data use agreement accordingly, will adjust it to say "limited data set" instead of "de-identified," and will re-submit it to our Legal office. You will need to submit an MDHHS IRB review application (attached) because this is considered research. You should also submit a "HIPAA Waiver Request" (attached). (I wasn't aware of the Waiver Request when we talked earlier this month.) Send those documents to me, and I'll pass them on to our IRB contact. I don't know whether you'll need to go through an IRB review with your institution.

In short, both your request and Dr. Hanna-Attisha's are in process in accordance with departmental policies.

I've attached a PDF that includes the numbers behind the graphs you referred to, and I'm CC'ing Dr. Hanna-Attisha so that she has it as well.

Please keep in mind that I work for a very small program responsible for processing several thousand blood lead results every week--in order to get them out to the professionals working directly with children and families, which is the primary purpose and highest priority of our program.

Bob

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

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Thursday, September 24, 2015 8:14 PM

To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Dear Robert,

I just spoke to this young researcher at Hurley, and apparently, she has been unable to get access to the state blood lead records.

I have to say, it is very disturbing that the state keeps issuing these blood lead reports and statements in their press releases, and refuses to share the data backing them up with outside researchers.

Even worse, state reps are running around claiming that these reports are proof that Flint water is safe to drink.

Can you tell me why it is so difficult to get this data, and why your agency is raising so many obstacles to sharing it with everyone who asks? I note that I have been asking to see your data since MDEQ first sent it to reporters back in August, and I count 10 e-mails that I sent responding to all your questions. As of yet, you have given me nothing in response. Yet you have been sending reporters one report after another. It seems your agency is more interested in public relations than sound science.

In the meantime, can I at least be given the numbers of EBL cases and number of tests each month, that are the basis for the latest graph your agency is sending to the press...or is that top secret as well?

Marc

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 25, 2015 1:19 PM
To: Minicuci, Angela (DCH); Peeler, Nancy (DCH)
Subject: RE: Flint follow-up

Angela,

I'm available today, but I'm no epidemiologist. The best I could say is something like this: "While the trend for Michigan as a whole has shown a steady decrease in lead poisoning year by year, smaller areas such as the city of Flint have their bumps from year to year while still trending downward overall."

Does that sound reasonable?

Bob

From: Minicuci, Angela (DCH)
Sent: Friday, September 25, 2015 1:13 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Peeler, Nancy (DCH) <PeelerN@michigan.gov>
Subject: FW: Flint follow-up
Importance: High

Hi Nancy and Bob,

The Detroit Free Press wants to do a bigger story about the issue of lead in Flint. I made it clear to her yesterday that we could not say the lead poisonings are related to the water, but she instead wants to do a story about the increase of overall lead poisonings in Flint between 12/13 and 14/15. Are either of you available to speak with her today?

Thank you,

Angela

From: Tanner, Kristi [<mailto:ktanner@freepress.com>]
Sent: Friday, September 25, 2015 12:16 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Subject: Flint follow-up

Hi Angela,

Thanks for the feedback yesterday. I took a look at the numbers last night that you sent over and the year over year increase between 13/14 and 14/15 is statistically significant $p < .05$

Can you ask you epidemiologist to confirm? Also, is this the first significant increase that Flint has seen for this cohort?

Thanks!

Kristi

(313) 222-8877 office

PPI cell

Children in Flint, less than 16 years of age, tested for lead

Children with Elevated BLL*

May 2010 - April 2011	168	0.043796
2011-2012	153	0.036085
2012-2013	118	0.028379
2013-2014	95	0.023691
2014-2015	123	0.032106
May - August 2015	34	0.029746

Children Tested**

May 2010 - April 2011	3,836
2011-2012	4,240
2012-2013	4,158
2013-2014	4,010
2014-2015	3,831
May - August 2015	1,143

*Each child counted only once.

**Some children counted in more than one year.

September 24, 2015

Source: MDHHS Data Warehouse

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 25, 2015 1:37 PM
To: Minicuci, Angela (DCH); Peeler, Nancy (DCH)
Subject: RE: Flint follow-up

Yes

From: Minicuci, Angela (DCH)
Sent: Friday, September 25, 2015 1:36 PM
To: Peeler, Nancy (DCH) <PeelerN@michigan.gov>
Cc: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Flint follow-up

Bob, I like what you had to say. That's basically what I told her, but she wants to hear it from someone other than a spokesperson ☺ Are you available for a call with her?

Angela

From: Peeler, Nancy (DCH)
Sent: Friday, September 25, 2015 1:20 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Cc: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: Re: Flint follow-up

I think Bob is the best person to speak to them about the lead data, if you are comfortable with that, Bob. My secret hope is that we can work in the fact that this pattern is similar to recent past. :)

Sent from my iPad

On Sep 25, 2015, at 1:12 PM, Minicuci, Angela (DCH) <MinicuciA@michigan.gov> wrote:

Hi Nancy and Bob,

The Detroit Free Press wants to do a bigger story about the issue of lead in Flint. I made it clear to her yesterday that we could not say the lead poisonings are related to the water, but she instead wants to do a story about the increase of overall lead poisonings in Flint between 12/13 and 14/15. Are either of you available to speak with her today?

Thank you,

Angela

From: Tanner, Kristi [mailto:ktanner@freepress.com]
Sent: Friday, September 25, 2015 12:16 PM
To: Minicuci, Angela (DCH) <MinicuciA@michigan.gov>
Subject: Flint follow-up

Hi Angela,

Thanks for the feedback yesterday. I took a look at the numbers last night that you sent over and the year over year increase between 13/14 and 14/15 is statistically significant $p < .05$. Can you ask your epidemiologist to confirm? Also, is this the first significant increase that Flint has seen for this cohort?

Thanks!

Kristi

(313) 222-8877 office

(586) 322-2094 cell

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Children with Elevated BLL*

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*Each child counted only once.

**Some children counted in more than one year.

September 24, 2015

Source: MDHHS Data Warehouse

Peeler, Nancy (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 25, 2015 1:56 PM
To: Peeler, Nancy (DCH)
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Thanks--he sent a couple of responses that I'll share on Monday. ☺

I did talk with the reporting, with Angela on the line. Answered some basic questions and didn't go out on any shaky limbs. The reporter wants to speak with Cristin Larder (maybe Monday—Angela said she knows Cristin), and I'm going to prepare a table of EBLs by year going as far back as possible, for Flint, plus Detroit and the state for comparison.

From: Peeler, Nancy (DCH)
Sent: Friday, September 25, 2015 1:50 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: Re: Automatic reply: New DCH-1294, time-sensitive

Really nice email, thanks!

Sent from my iPad

On Sep 25, 2015, at 12:44 PM, Scott, Robert L. (DCH) <ScottR9@michigan.gov> wrote:

Marc,

As you well know, the data you and Dr. Hanna-Attisha have requested are derived from personal health data, which of course is confidential. There are state and federal laws governing what can be shared, and how, with researchers or the public.

I worked with you earlier this month to get data to you relatively quickly, but we did not manage to complete the process before I went on annual leave for several days. I neglected to inform you that I'd be away. I returned on Wednesday and corresponded that day with Dr. Hanna-Attisha, providing her with the forms she'll need for her request.

Regarding your email from Monday, I think you'll be able to get approval for data with zip code identified. I'll edit your data use agreement accordingly, will adjust it to say "limited data set" instead of "de-identified," and will re-submit it to our Legal office. You will need to submit an MDHHS IRB review application (attached) because this is considered research. You should also submit a "HIPAA Waiver Request" (attached). (I wasn't aware of the Waiver Request when we talked earlier this month.) Send those documents to me, and I'll pass them on to our IRB contact. I don't know whether you'll need to go through an IRB review with your institution.

In short, both your request and Dr. Hanna-Attisha's are in process in accordance with departmental policies.

I've attached a PDF that includes the numbers behind the graphs you referred to, and I'm CC'ing Dr. Hanna-Attisha so that she has it as well.

Please keep in mind that I work for a very small program responsible for processing several thousand blood lead results every week--in order to get them out to the professionals working directly with children and families, which is the primary purpose and highest priority of our program.

Bob

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

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Thursday, September 24, 2015 8:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Dear Robert,

I just spoke to this young researcher at Hurley, and apparently, she has been unable to get access to the state blood lead records.

I have to say, it is very disturbing that the state keeps issuing these blood lead reports and statements in their press releases, and refuses to share the data backing them up with outside researchers.

Even worse, state reps are running around claiming that these reports are proof that Flint water is safe to drink.

Can you tell me why it is so difficult to get this data, and why your agency is raising so many obstacles to sharing it with everyone who asks? I note that I have been asking to see your data since MDEQ first sent it to reporters back in August, and I count 10 e-mails that I sent responding to all your questions. As of yet, you have given me nothing in response. Yet you have been sending reporters one report after another. It seems your agency is more interested in public relations than sound science.

In the meantime, can I at least be given the numbers of EBL cases and number of tests each month, that are the basis for the latest graph your agency is sending to the press...or is that top secret as well?

Marc

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.

<HIPAA Waiver Request Template.doc>

<Flint Testing and EBLs_updated 092315_with notes.pdf>

<DCH-1277 IRB Initial Review Application.doc>