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bjRe: Citizen concern, Reminders: IRB Addendum to Update Study protocol, Monthly Reports
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Dat
e: Fri, 23 Dec 2016 02:22:53 +0000

Fro
m: Wells, Eden (DHHS) <WellsE3@michigan.gov>

To: Shawn McElmurry <s.mcelmurry@wayne.edu>

CC: LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>, Paul

:Kilgore <paul.kilgore@wayne.edu>, matthew.seeger@wayne.edu <matthew.seeger@wayne.edu>, MZERVOS1@hfhs.org <MZERVOS1@hfhs.org>, masten@egr.msu.edu <masten@egr.msu.edu>, nglove@umich.edu <nglove@umich.edu>, Beach, Michael J. (CDC/OID/NCEZID) <mjb3@cdc.gov>, durno.mark@epa.gov <durno.mark@epa.gov>, Yoder, Jonathan S. (CDC/OID/NCEZID) <jevy9@cdc.gov>, McFadden, Jevon (DHHS-Contractor) <McFaddenJ1@michigan.gov>, Feighner, Bryce (DEQ) <FEIGHNERB@michigan.gov>

And to further clarify Shawn – my response here below was to your detection of E. coli in the water not just a low chlorine residual.

Sent from my iPhone, please excuse typos

Eden V. Wells, MD, MPH, FACPM
Chief Medical Executive
Michigan Department of Health and Human Services
Tel: 517-335-8011

On Dec 22, 2016, at 4:43 PM, Wells, Eden (DHHS) <WellsE3@michigan.gov> wrote:

Hi Shawn-

I would recommend that the residence boil water until cleared by the City/DEQ; per their testing protocols. Sound ok? It may differ according to the extent of the problem of an e.coli test is positive (other residences, water mains, etc).

Ian- this is enough for my approval with the statement I made above- is that ok?

Sent from my iPhone, please excuse typos

Eden V. Wells, MD, MPH, FACPM
Chief Medical Executive
Michigan Department of Health and Human Services
Tel: 517-335-8011

On Dec 22, 2016, at 12:57 PM, Shawn McElmurry <s.mcelmurry@wayne.edu> wrote:

Ian and Eden, please see attached Research Revision Request. The proposed revisions clarify the timeliness of reporting chlorine and e.coli levels. Please let me know if more information is needed. Sincerely,

Shawn McElmurry



Subject:Re: Citizen concern, Reminders: IRB Addendum to Update Study protocol, Monthly Reports

Date:Fri, 23 Dec 2016 02:41:27 +0000

From:Wells, Eden (DHHS) <WellsE3@michigan.gov>

To:Shawn McElmurry <s.mcelmurry@wayne.edu>

CC:LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>, Paul Kilgore <paul.kilgore@wayne.edu>, Nancy Love <nglove@umich.edu>, Matthew Seeger <matthew.seeger@wayne.edu>, Marcus Zervos <MZERVOS1@hfhs.org>, Susan Masten <masten@egr.msu.edu>, Beach, Michael J. (CDC/OID/NCEZID) <mjb3@cdc.gov>, McFadden, Jevon (DHHS-Contractor) <McFaddenJ1@michigan.gov>, Yoder, Jonathan S. (CDC/OID/NCEZID) <jey9@cdc.gov>, Feighner, Bryce (DEQ) <FEIGHNERB@michigan.gov>, durno.mark@epa.gov <durno.mark@epa.gov>

No worries – I can always use it quite a bit of education on this and I would love to talk more to Susan or perhaps we could all have a group meeting! And my sincere apologies I was referring to the detection of E. coli are and everything should remain as we discussed with regarding the additional testing if you report low chlorine residuals to the city and environmental agencies.

Whoever one please have a happy holidays. Sean, I really respect your dedication and your hard work on all of this – **now we can both sign off and enjoy the evening! And a wonderful wonderful Holiday season!**

Sent from my iPhone, please excuse typos

Eden V. Wells, MD, MPH, FACPM
Chief Medical Executive
Michigan Department of Health and Human Services
Tel: 517-335-8011

On Dec 22, 2016, at 9:25 PM, Shawn McElmurry <s.mcelmurry@wayne.edu> wrote:

Sorry, I did not see where you indicated a positive e.coli test was required before a boil water advisory was issued. I agree, if a e.coli test comes back positive, then yes, recommending the resident boil their water is absolutely required. Based on your email below, I got the impression you were recommending residents boil water if the chlorine level comes back less than 0.2 mg/L, regardless of any biological testing.

With regard to the use of the filters, the main difference between Flint and Ann Arbor is that Ann Arbor isn't issuing filters to residents in order to achieve compliance with drinking water regulations. Susan (cc'd) is much more an expert on this part of the regulations but I know she is traveling until the end of the month...I would suggest we postpone this part of the discussion until after the holidays, and not via email.

Sorry for the confusion. **Now...really, have a happy holidays!**

Shawn

From: Wells, Eden (DHHS) [mailto:WellsE3@michigan.gov]

Sent: Thursday, December 22, 2016 9:04 PM

To: Shawn McElmurry <s.mcelmurry@wayne.edu>

Cc: LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Paul Kilgore <paul.kilgore@wayne.edu>; Nancy Love <nglove@umich.edu>; Matthew Seeger <matthew.seeger@wayne.edu>; Marcus Zervos <MZERVOS1@hfhs.org>; Susan Masten

<masten@egr.msu.edu>; Beach, Michael J. (CDC/OID/NCEZID) <mjb3@cdc.gov>; McFadden, Jevon (DHHS-Contractor) <McFaddenJ1@michigan.gov>; Yoder, Jonathan S. (CDC/OID/NCEZID) <je9@cdc.gov>; Feighner, Bryce (DEQ) <FEIGHNERB@michigan.gov>; durno.mark@epa.gov

Subject: Re: Citizen concern, Reminders: IRB Addendum to Update Study protocol, Monthly Reports

Shawn – I am not an expert in this field so I may be not interpreting your email very well. What you're stating about filters is true, isn't it, for any filter use anywhere across the country. And that has not been the recommendation to date, although filter should be maintained as instructed with the appropriate care whether or not you are on municipal or well water.. This is the type of thing that I believe CDC experts from waterborne disease were discussing with your team and Dr. Love last month?

The boil filtered water message addressed below was for if you have a low chlorine with a positive E. coli which of course must be reported to the city and then must be addressed by DEQ And EPA if needed. That's why I said that we don't have a standing response because there will be more data and response that will be required from other regulatory agencies that are doing the testing to assess if there's truly a microbiologic problem.

Temporarily – if you actually find E. coli in someone's home there should be a temporary boil of filtered water until the city and agencies can confirm. That said – you should already have notified the agencies about the low chlorine residual and therefore they should be already out there and collecting samples. But maybe I'm confused so I'm bringing these experts onto this email – you yourself stated that you've not been able to find an association of residual chlorine and bacterial growth... So what is different about a filter use in Flint then and Ann Arbor for example?

I'm a resident of Ann Arbor and would have major concerns about Dr. Love's studies of the same issue here that you are bringing up for Flint. Should I be doing chlorine test on my wire if I use a filter here in A2? Or in Mississippi? Essentially you are telling me that if I use a filter here I should be boiling water as well?

Again, extrapolating your filter studies into potential individual or PH health impacts needs to be supported by data or national waterborne disease experts, or studies that have been conducted about filter use and bacteria over the last two decades which I thought show the same findings that you are bringing up.

Please forgive me if I'm missing something as again you are much more expert on water quality – am I missing something?

Eden

On Dec 22, 2016, at 8:32 PM, Shawn McElmurry <s.mcelmurry@wayne.edu> wrote:

A couple of quick thoughts (note: I removed some from the state on this thread and I have added others from FACHEP – didn't want to clog everyone's inboxes):

First, it is well known that the amount of bacteria in water increases across the type of PoU filters used in Flint. In fact these filters are not certified to protect against organisms. We have confirmed this to be true in Flint as well as part of our NSF funded research. Second, the filters also eliminate residual chlorine. So far we cannot find an association between that the amount of residual chlorine entering the filters and the concentration of bacteria leaving the filter. Therefore, every one using filters in Flint is being exposed to an increased number of bacteria

and water that has zero residual chlorine. Therefore, should everyone using a filter in Flint employ a secondary form of disinfection (e.g. boiling water)?

Well water does not have chlorine in it. Are you advising that when we sample residents on well water near Flint, that we advise them to boil their water?

I am not aware of any standards that require residents to boil water if residual chlorine is below 2 mg/L at a residential tap. That being said, the deployment of PoU filters across a distribution system, as has been done in Flint, is unprecedented. This is obviously required to mitigate the risk to Pb, and previously DBPs. This has extended the treatment system into residential homes, to the outlet of the PoU device since the PoU device is providing required treatment. Based on the Surface Water Treatment Rule, a detectable level of chlorine or an HPC <500 CFU/mL is required throughout the distribution system. HPC counts are far above 500 CFU/ml in Flint's system. Therefore, based on this rule, a residual level of chlorine is required throughout the drinking water system...which now extends to the outlet of the PoU devices.

Sorry to bring this up again before the holiday. I wish you both a merry Christmas and a happy New Year!

Shawn

Ps. I am out of the office all day tomorrow. We are not planning on sampling until after the first of the year so I do not see this impacting our sampling...but obviously this is something that needs to be resolved.

From: Wells, Eden (DHHS) [<mailto:WellsE3@michigan.gov>]
Sent: Thursday, December 22, 2016 6:58 PM
To: LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>
Cc: Shawn McElmurry <s.mcelmurry@wayne.edu>; Horste, Ian (DHHS) <Horstel@michigan.gov>; MDHHS-IRB <MDHHS-IRB@michigan.gov>; Hanley, Farah (DHHS) <hanleyf@michigan.gov>; Van Winkle, Jessica (DHHS) <VanWinkleJ@michigan.gov>; Paul Kilgore <paul.kilgore@wayne.edu>
Subject: Re: Citizen concern, Reminders: IRB Addendum to Update Study protocol, Monthly Reports

ABSOLUTELY!!!!!!!

Sent from my iPhone, please excuse typos

Eden V. Wells, MD, MPH, FACPM

Chief Medical Executive

Michigan Department of Health and Human Services

Tel: 517-335-8011

On Dec 22, 2016, at 6:54 PM, LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov> wrote:

Boil their filtered water, correct?

From: Wells, Eden (DHHS)

Sent: Thursday, December 22, 2016 4:44 PM

To: Shawn McElmurry <s.mcelmurry@wayne.edu>

Cc: Horste, Ian (DHHS) <Horstel@michigan.gov>; MDHHS-IRB <MDHHS-IRB@michigan.gov>; Hanley, Farah (DHHS) <hanleyf@michigan.gov>; Van Winkle, Jessica (DHHS) <VanWinkleJ@michigan.gov>; LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Paul Kilgore <paul.kilgore@wayne.edu>

Subject: Re: Citizen concern, Reminders: IRB Addendum to Update Study protocol, Monthly Reports

Hi Shawn-

I would recommend that the residence boil water until cleared by the City/DEQ; per their testing protocols. Sound ok? It may differ according to the extent of the problem of an e.coli test is positive (other residences, water mains, etc).

Ian- this is enough for my approval with the statement I made above- is that ok?

Eden V. Wells, MD, MPH, FACPM

On Dec 22, 2016, at 12:57 PM, Shawn McElmurry <s.mcelmurry@wayne.edu> wrote:

Ian and Eden, please see attached Research Revision Request. The proposed revisions clarify the timeliness of reporting chlorine and e.coli levels. Please let me know if more information is needed.

Sincerely,

Shawn McElmurry

From: Wells, Eden (DHHS) [<mailto:WellsE3@michigan.gov>]

Sent: Thursday, December 22, 2016 11:54 AM

To: Horste, Ian (DHHS) <Horstel@michigan.gov>; Shawn McElmurry <s.mcelmurry@wayne.edu>

Cc: Hanley, Farah (DHHS) <hanleyf@michigan.gov>; Van Winkle, Jessica (DHHS) <VanWinkleJ@michigan.gov>; LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Paul Kilgore <paul.kilgore@wayne.edu>

Subject: RE: Citizen concern, Reminders: IRB Addendum to Update Study protocol, Monthly Reports

Importance: High

Dear Ian,

We are very concerned regarding the delay in getting the updated IRB protocol/contract amendment. I just talked with Shawn and he is out of the office. CC'ing Paul as well. We asked for these at our FACHEP meeting last week on Friday as well.

Shawn, we need this ASAP. **There is a concern regarding federal non-compliance.**



Eden

From: Horste, Ian (DHHS)

Sent: Thursday, December 22, 2016 10:56 AM

To: Wells, Eden (DHHS) <WellsE3@michigan.gov>

Subject: RE: Citizen concern, Reminders: IRB Addendum to Update Study protocol, Monthly Reports

Hello Eden,

I appreciate your efforts to keep in touch with the investigators. From the human research protections side of this discussion, I have two areas of concern with this project:

1. Changes to approved research protocols or approved study documents must receive IRB approval (from all reviewing IRBs) prior to implementation. The only exception is when a change is necessary to eliminate apparent immediate hazards to research subjects. Even in the case of a change made under this exception, the investigator or Responsible Department Employee must contact the IRB regarding the change as soon as possible (usually within 48 hours). I am unsure if changes to any of the three approved studies have occurred, but if interactions with subjects or approved study documents may have changed without IRB approval that would constitute non-compliance federal regulations.

2. During the conference call I was present for there was discussion that there may need to be broader reporting of certain identifiable water quality test results to public health or environmental protection agencies than were initially appreciated. The development of those notification strategies will be an essential addendum to the protocol, and (importantly from a human research protections standpoint) any potential for disclosure of identifiable information may need to be conveyed more directly to the potential subjects of the research during the informed consent process. From your messages on this topic, it

appears you are still awaiting revisions addressing this concern.

Given prior discussions I was under the impression changes were likely and would be made on an accelerated timeline. My hope is to ensure if those changes are proposed that our IRB will be notified to provide review and approval. If that will not be occurring, it will be helpful to confirm the research is continuing as originally documented.

I am available to review documents or formal research revision requests, and am willing to provide guidance in support of the continued ethical conduct of this research. Please let me know if you or the investigators have additional insight on how the study is progressing, or if there is any way I can be of assistance.

Thank you,

-lan

From: Wells, Eden (DHHS)

Sent: Monday, November 21, 2016 12:40 PM

To: Horste, lan (DHHS) <Horstel@michigan.gov>; Shawn McElmurray <s.mcelmurry@wayne.edu>

Cc: Paul Kilgore <paul.kilgore@wayne.edu>; matthew.seeger@wayne.edu; Marcus Zervos <MZERVOS1@hfhs.org>; LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Waggoner, Carrie (DHHS) <WaggonerC@michigan.gov>; Van Winkle, Jessica (DHHS) <VanWinkleJ@michigan.gov>

Subject: Citizen concern, Reminders: IRB Addendum to Update Study protocol, Monthly Reports

Importance: High

Shawn,

We still have not received an update to your study protocol using the form lan sent, regarding the increased timely response to chlorine levels.. It has been a week since he sent it and a month since discussed. Please do ASAP, this has IRB implications.

Once that is sent and the IRB updated, Jessica can open the grant on line and you can update the contract in that system.

Further, while I bypassed the need to do a FACHEP Monthly Report for October due to all of the calls we needed on your protocols, we are expecting a Monthly Report for November by December 1, which can include any activities for October.

Also- I received word today that EPA Region V has gotten a complaint/concern from a citizen in Flint about a Legionella Detect reported from her showerhead. She is uncertain as to the meaning of the findings. The report said that this detect information was shared with GCHD— we do not have such information, and I have advised EPA that we are unable to respond to this type of concern on behalf of the resident without the appropriate information and likely all of the limitations due to the PO.

Eden V. Wells, MD, MPH, FACPM

From: Horste, Ian (DHHS)
Sent: Monday, November 14, 2016 12:03 PM
To: Wells, Eden (DHHS) <WellsE3@michigan.gov>; Shawn McElmurray <s.mcelmurry@wayne.edu>
Cc: Paul Kilgore <paul.kilgore@wayne.edu>; matthew.seeger@wayne.edu; Valacak, Mark <MVALACAK@gchd.us>; LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Waggoner, Carrie (DHHS) <WaggonerC@michigan.gov>
Subject: RE: IRB Addendum to Update Study protocol

I apologize for not following up more quickly. The MDHHS IRB does ask that requests for changes to approved research be submitted with a DCH-1478 (attached). Please don't hesitate to let me know if there are questions or concerns on this.

Regards,

-Ian

Ian A. Horste, MPH

Institutional Review Board Administrator/Chair

Michigan Department of Health and Human Services

From: Wells, Eden (DHHS)
Sent: Thursday, November 10, 2016 5:40 PM
To: Shawn McElmurray <s.mcelmurry@wayne.edu>
Cc: Paul Kilgore <paul.kilgore@wayne.edu>; matthew.seeger@wayne.edu; Valacak, Mark <MVALACAK@gchd.us>; LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Horste, Ian (DHHS) <Horstel@michigan.gov>; Waggoner, Carrie (DHHS) <WaggonerC@michigan.gov>
Subject: IRB Addendum to Update Study protocol

Good evening,

Sarah and I were doing our updates today and realized we have not heard back about receiving the revision to the IRB study protocol as you outlined after our latest call.

There is an IRB revision form and Ian can send that to you, or even if you could forward a document outlining how the protocol is being updated that would be great-unless Ian states that this has to be on the revision form.

Eden V. Wells, MD, MPH, FACPM

Shawn McElmurry

From: Shawn Patrick McElmurry
Sent: Saturday, October 29, 2016 11:05 AM
To: Zervos, Marcus
Subject: RE: Response to Eden's most recent email

Ok. So you're good with email. Does it go far enough?

From: Zervos, Marcus [mailto:MZERVOS1@hfhs.org]
Sent: Saturday, October 29, 2016 11:04 AM
To: Shawn Patrick McElmurry <s.mcelmurry@wayne.edu>; Matthew Seeger <matthew.seeger@wayne.edu>; Paul Evan Kilgore <paul.kilgore@wayne.edu>; Susan Masten <masten@egr.msu.edu>; Nancy Love <nglove@umich.edu>; Laura Sullivan (dr.laura2@gmail.com) <dr.laura2@gmail.com>; Benjamin Pauli (bpauli@kettering.edu) <bpauli@kettering.edu>; Joanne Sobeck <ab1350@wayne.edu>; Sammy Zahran <Sammy.Zahran@colostate.edu>
Subject: RE: Response to Eden's most recent email

Shawn you have my thoughts on response to her,

From: Shawn Patrick McElmurry [mailto:s.mcelmurry@wayne.edu]
Sent: Saturday, October 29, 2016 10:50 AM
To: Matthew Seeger <matthew.seeger@wayne.edu>; Paul Evan Kilgore <paul.kilgore@wayne.edu>; Zervos, Marcus <MZERVOS1@hfhs.org>; Susan Masten <masten@egr.msu.edu>; Nancy Love <nglove@umich.edu>; Laura Sullivan (dr.laura2@gmail.com) <dr.laura2@gmail.com>; Benjamin Pauli (bpauli@kettering.edu) <bpauli@kettering.edu>; Joanne Sobeck <ab1350@wayne.edu>; Sammy Zahran <Sammy.Zahran@colostate.edu>
Subject: Response to Eden's most recent email
Importance: High

All, I apologize for bringing all of you into this conversation but I would like the collective insight of our lead investigators. As many of you know, last Friday Matt, Mark, Paul and I were subjected to an emergency conference call with MDHHS representatives at the bequest of Eden Wells. This was the latest in a series of demands/inquiries from the state that have been increasing over the last few weeks. Below is the latest email from Eden.

I feel the need to push back on this. It is becoming extremely difficult to do anything but respond to her demands. I am not opposed to finding ways to share data more rapidly as long as it is done simultaneously with other partners (including residents!).

After reading the email below, please review the attached draft response. While I REALLY need to spend some time with my family tomorrow, I could discuss via phone today if interested.

Thanks for your guidance.

Shawn

From: Wells, Eden (DHHS) [mailto:WellsE3@michigan.gov]
Sent: Saturday, October 29, 2016 8:47 AM
To: Shawn Patrick McElmurry <s.mcelmurry@wayne.edu>
Cc: LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Paul Evan Kilgore <paul.kilgore@wayne.edu>; Matthew Seeger <matthew.seeger@wayne.edu>; MZERVOS1@hfhs.org; Horste, Ian (DHHS) <Horstel@michigan.gov>; Moran, Susan

(DHHS) <MoranS@michigan.gov>; Waggoner, Carrie (DHHS) <WaggonerC@michigan.gov>; Rockefeller, Cheryl (DHHS) <RockefellerC@michigan.gov>; Hanley, Farah (DHHS) <hanleyf@michigan.gov>
Subject: Re: 3 PM Draft Agenda

Good morning,

Per our call last Friday, this absolutely does have IRB ramifications, which is why we had the call. The individual and public health ramifications of your study, which became apparent immediately at the time of your press release must be addressed immediately.

This was the agreement per our call. The addendum to the contract will refer to the update required in your study protocol, which needs to be submitted to MDHHS IRB, and which must address the timely manner in which individual houses are identified and reported in a timely manner to Public Health, City, DEQ and EPA, should a health risk be determined by your study.

There are no ramifications regarding the data use agreement as your household study is not part of any data use agreement with our Department.

This cannot await a discussion on November 4. One of the outcomes of the call is that you stated that you will be able to revise the protocol to allow timely household identification should you identify a health threat, that all were going to think about how best to do this over last weekend, and that you were going to address this early last week.

Given that this does have IRB ramifications should highlight the urgency of this matter, as the IRB assures the health and safety of study participants. The addendum/ adjustment to the protocol should be addressed urgently by FACHEP.

Eden V. Wells, MD, MPH, FACPM
Chief Medical Executive
Michigan Department of Health and Human Services
Tel: 517-284-4020

Sent from my iPhone, please excuse typos

On Oct 28, 2016, at 9:14 PM, Shawn Patrick McElmurry <s.mcelmurry@wayne.edu> wrote:

Eden, as you know amending the study protocol impacts the IRB, DUA, and other aspects of our project. This is something that apparently needs to be discussed further.

I believe we have FWICC Friday (11/4). How about meeting in person prior to FWICC to discuss?

Shawn

From: Wells, Eden (DHHS) [mailto:WellsE3@michigan.gov]
Sent: Friday, October 28, 2016 3:32 PM
To: Shawn Patrick McElmurry <s.mcelmurry@wayne.edu>
Cc: LyonCallo, Sarah (DHHS) <lyoncallos@michigan.gov>; Paul Evan Kilgore <paul.kilgore@wayne.edu>; Matthew Seeger <matthew.seeger@wayne.edu>; MZERVOS1@hfhs.org; Horste, Ian (DHHS) <Horstel@michigan.gov>; Moran, Susan (DHHS) <MoranS@michigan.gov>; Waggoner, Carrie (DHHS) <WaggonerC@michigan.gov>; Rockefeller, Cheryl (DHHS) <RockefellerC@michigan.gov>; Hanley, Farah