STATE OF MICHIGAN

IN THE 61ST DISTRICT COURT FOR THE CITY OF GRAND RAPIDS

PEOPLE OF THE STATE OF MICHIGAN,

Dist. Ct. No. 17T-135-FY

v

DR. EDEN VICTORIA WELLS,

Defendant.
_____/

CONFERENCE CALL

October 21, 2016, at 3:00 p.m.

TRANSCRIBED BY: MS. SUSAN M. MASON, CER 3266
Certified Electronic Recorder
(616) 204-5101

DR. WELLS: Good afternoon.

DR. MCELMURRY: Hello, this is Shawn.

DR. WELLS: Hi Shawn, it's Eden Wells. I'm going to put you on mute for--yeah, we just a hi there, a little background noise, we'll wait about another minute or two to get rolling. Did you all get a copy of my agenda?

DR. MCELMURRY: I did, I did. And real quick, just so you know, I think almost all of us on our end have like 30 minutes. So there's a lot here, and I think we're going to have to meet again to go through it in more detail, it's obvious, and I really appreciate you putting the time and, you know, getting all of the stuff down. So, we'll get through what we can. I'm going to put you guys on mute, so you don't hear the airport behind me and then I'll try to chime in whenever I'm cued or whenever necessary, okay?

DR. WELLS: Well, what we'll do then is we'll run quickly through the agenda, or we'll go quickly through the subjects and then try to get done in a half an hour, but definitely we'll want to bring up the issues and then need to figure out next steps. Putting you on mute--

DR. MCELMURRY: Yeah, yeah.

DR. WELLS: We'll put you on mute for a second or two and awaiting some other folks.

DR. MCELMURRY: Okay. All right. Thanks.

DR. WELLS: Where is Sarah?

UNIDENTIFIED SPEAKER: So is he on mute?

DR. WELLS: Um hm.

UNIDENTIFIED SPEAKER: What's the deal?

DR. WELLS: He says he can only meet for a half an hour.

UNIDENTIFIED SPEAKER: Is that Shawn?

DR. WELLS: Yeah.

UNIDENTIFIED SPEAKER: What the hell?

DR. WELLS: Um hm. We're just going to say sorry buds.

UNIDENTIFIED SPEAKER: This is one of the most important things in his day.

DR. WELLS: And I would recommend though that if anybody can stay past 3:30 that it would be highly important that you do so. If we have to go that far. We're the ones funding them. Where is Sarah?

UNIDENTIFIED SPEAKER: The room changed, didn't it?

DR. WELLS: Um um.

UNIDENTIFIED SPEAKER: Oh, it was--

DR. WELLS: I just wanted to make sure you guys knew.

DR. ZERVOS: Hello?

DR. WELLS: Hi, it's Dr. Wells. Just waiting for--

DR. ZERVOS: Hi, Eden. It's Mark Zervos. I'm on

the line.

DR. WELLS: Okay, thanks. We're going to get started in just another minute or two.

DR. ZERVOS: Okay.

DR. WELLS: I just texted Sarah, I don't know what the deal is. I'm going to get started for the sake of time. Who else did we have?

All right. This is Dr. Wells, and I'm just going around on the phone line, and then we'll talk about whoever is here in the room.

I heard Dr. Zervos, and Dr. McElmurry. Anybody else?

(No audible response)

DR. WELLS: Is there nobody else on the line from FACHEP?

DR. KILGORE: Hi. This is Paul Kilgore. How are you?

DR. WELLS: Good. I've got you on there. Okay? Anybody else?

DR. KILGORE: I'm just out--I'm out on north campus of the University of Michigan in public space.

DR. WELLS: Okay.

DR. KILGORE: It's the only place there's cell phone reception and--despite it being the engineering area.

DR. WELLS: Yeah, I know that dead zone very well.

Okay.

DR. SEEGER: And this is Matt, I'm in my office.

DR. WELLS: All right. Anybody else from FACHEP calling in?

DR. SEEGER: Yeah, Shawn will be calling in and Mark is able to call in.

DR. ZERVOS: Yeah, I'm on.

DR. WELLS: They're both on the call. So we have Shawn, Marcus, Paul and Matt. Anybody else?

(No audible response)

DR. WELLS: Okay. We have myself here in the room, Eden Wells. Cheryl Rockefeller is with me taking notes and just recording the call for purposes of documentation. We will share all the minutes with you and everybody will have a chance to edit.

To my right, do you want to?

MR. HORSTE: Sure. Ian Horste, from the Michigan Department of Health and Human Services Institutional Review Board.

MS. VAN WINKLE: Jessica Van Winkle, from DHHS Financial Operations.

MS. HENSLER: Jeanette Hensler, from the Bureau of Purchasing Grants Division.

MS. HANLEY: Farah Hanley, with Department Operations.

DR. WELLS: Excellent. So, just going to get started. The purpose of this is to review the issues that have arisen regarding the FACHEP study protocols. I have a copy of it here. But we're going to make this fairly quick. I know you are time limited, but I think that the matters of our--pretty critical importance at this point, and so I'm hoping that perhaps, while I realize you have other meetings, we do too, and we've been able to put them aside to address these issues in the timely fashion that they need to be.

I had several issues regarding the study protocol prior to yesterday evening when Sarah Lyon Callo recognized a data breach. I would have not have had this call today except for the fact that the data breach did occur, which led to the third and now possibly fourth potential issue on the protocol that needs to be addressed immediately. I was hoping that some of this other stuff could wait for a couple days, because I know that I've been providing you long-winded emails about the importance of the public health implications of your study.

I want to then just lead, just as a personal note, there's been a lot of conversation since the first U of M study, which is not funded by us, has come out with some feeling among our staff here, and including myself, that there's a number of your team that feels like this is our

first rodeo when it comes to research or investigational review boards.

Do know that we have a number of decades of experience in reviewing protocols, that we work with institutions not only throughout this state, but national renowned institutions throughout this country. We know how to do public health--no, I'm speaking. We know how to do public health study protocol development, we know how that it's supposed to be established. We request the very highest integrity of the science and the ethics that are involved.

This is the first time in my experience, starting this summer, that we have had to extensively revise study protocols and data use agreements over and over again with an academic institution.

Even doing so, because of that experience, we were very concerned about the implementation of this protocol, so I would like to go into the issues that have come arised, and I did--somebody was trying to step in. Is someone wanting to make a comment?

(No audible response)

Okay. I'm going to move on, study protocol issues. Under the environmental monitoring and residence survey protocol, randomization strategy. One of the things that have come up that was discussed with me with a water

engineer expert, Shawn, is there is not very much clarity with the data that you currently have that fed the press release that was released two days ago. How randomized your group was and whether all of these cases represented a certain cohort.

When I look through the protocol you have initial statement on page 21, that you're going to have a randomized household study. On page 36, it then states that you're having a randomized stratified study with two tiers, 50 percent of which will be in a low chlorine environment, or perhaps a high density of vacant households, and the other, tier two, would be in "other Flint households".

Our question is at this point, one, is in the results for the press release that occurred there has been some questions as to what households did that data represent. Can you--do you have that information?

DR. MCELMURRY: Eden, this is Shawn. So thanks a lot of for bringing all of this up, and I'm happy to try to address this as best I can. I did send an email late last night that I thought addressed this. It is difficult for us to be able to tell right now because of the way we identify our samples. So we will be able to tell you exactly how those samples are selected, where they were collected, and that kind of information. But as of right now, I can't tell you, per se, that, you know, 20 percent is with this, and 10

percent is with this strategy.

From an engineering perspective, it really didn't matter, it was far beyond what it normally--what would normally be expected within a water distribution system and that's why we thought it was important to relay that information to the public and the water utility.

DR. WELLS: Okay. I'm not really going into the nature of why the press release, because I think we're all in agreement with that, what I'm going back to is the study protocol.

So the protocol outlines a randomization strategy. Can you--I guess the concern is--

DR. MCELMURRY: Sure.

DR. WELLS: --is that there a randomization strategy being conducted? Because, if so, there should be randomized samples from both tiers, as well as outside of the city, and as well as in another control group, I guess it's Control Group A and then Control Group B. But the two tiers should also be sufficiently randomized.

The reason why I'm asking this is the question is do you have a randomized two tier study, or is it a randomized two tier cluster household study?

DR. MCELMURRY: So we have--both are randomized. So let me explain, so we have one population, the entire city, we'd just randomly select addresses, okay? So that's

the one-half of the in the city. Outside of the city, it's all randomized for the other areas, okay?

So, inside the city, there's half the samples are purely randomized, and then we have another selection process where we take a--the water age, the chlorine levels, and then the housing density, and--or vacancy rate, excuse me, and then we create a Z-score for those values and we take those three Z-scores, we essentially multiply them together, this is my understanding, I'm sure a statistician could clarify this for me, created distribution and randomly sampled from that distribution.

DR. WELLS: Okay. So--and right now you--then how are--I guess the question is so somebody is doing this randomization for you, and then you're getting a list of households for which you'll send teams out to go sample?

DR. MCELMURRY: That's exactly right.

DR. WELLS: Okay.

DR. MCELMURRY: That's exactly right.

DR. WELLS: So you were basically conducting a randomized study plus a randomized--I'm going to assume there's going to have to be a cluster component in there because of the spacial clustering of these chlorine areas, your Z-scores? You're not aware of what that's involving?

DR. MCELMURRY: No, I mean, those are the three factors that we essentially generate a score for each area

and then I believe--I believe it's at maybe a percentage track (ph), it might be at the block group, however, I can't remember the exact level at which those, these scores are scored, and from those groups we then basically randomize--be kind of like a weighted randomization for those areas. Does that make sense?

DR. WELLS: Yeah, it does. I don't--I'll defer to any of the EPI's or statisticians, but it seems that one of the questions I would have is how well the randomization is occurring in the different sized clusters, unless your clusters are actually made even. By population.

MR. MCELMURRY: So in the interest of time, why don't I have our statistician, Sammy Zahran, provide a written explanation of how that's done.

DR. WELLS: Okay, that would be great. Yeah, if you could just please provide the strategy, this keeps coming up with our--the engineers and water quality experts and I was not part of that phone call that you had the other day, but we did--it did prompt us to go back to the protocol and insure that, in fact, you're conducting a randomized strategy, which it sounds like you are. The only concern I would have is if the clusters are not--are being treated independently.

Did you have anything else to add to that, Sarah?

MS. CALLO: No, go ahead.

DR. WELLS: Okay. All right. So very good. The next issue, and this was a very strong component of what was requested by the leadership of the several departments at the state, and certainly those of funding entities, is that the control protocol must be part of this study, so it sounds like you still don't know how many cases are--in the press release were in Tier 1, Tier 2, Area A or Area B?

DR. MCELMURRY: So I can tell you the last time I checked we had 25 percent of our samples from the control area.

DR. WELLS: Which one--

DR. MCELMURRY: We have had a very big challenge in trying to get sampling from the control group, we've had overwhelming response to our--our response in Flint. Response outside of the area has been challenging. We've been addressing that with improved recruitment strategies and that has been getting much much better over time. We're still not to the 50, you know, percent, the equal

distribution that we'd like, but it's--I'm sure it's over 25 percent based on the last time I checked now.

DR. WELLS: Okay. So that would be Control A, is the 25 percent of your samples of the 78 households that were in Control A?

DR. MCELMURRY: That's right.

DR. WELLS: Okay, thanks. All right. So this--

the issue we're having here, as you know, and I realize--I know you've discussed the issue of difficulty obtaining controls, however as part of it, under the contract as well as the IRB, the randomized control aspects must be conducted in a fashion that maintain the internal and external validity of the study. So when, you know, for instance, Control Area B needs to probably be sampled during the same time frame as Control A, as Tier 1, as Tier 2, because you're going to run into seasonal fluctuations and perhaps temporal or historical changes in the water lines or the areas of the homes.

Again, I've got smarter epidemiologists than I in the room, but am I capturing that correctly?

(No audible response)

Okay. People are nodding here. So I do realize that you were stating that it's difficult to do, we do know the controls. I know we were talking with the CDC and it takes like 3,000 calls to get enough for controls to do even a food-borne study, but that's the nature of the beast. And so my concern is that there is, you know, the press release sort of brought it up, and again no problems with the press release itself, but the idea that as data continues to be analyzed with context or controls, the inability to adequately interpret that data, or that public health importance, gets very difficult. And my worry is that

FACHEP will be putting the emphasis on the control investigation onto the back burner. And that would include Area B, I'm glad to hear that there's progress in Area A.

DR. MCELMURRY: Yes. And all I can say is that we share your concerns and we are working as hard as we can, given the resources we have to do that, and, yes, we'd share that and we recognize that.

DR. WELLS: Okay, great. Thank you. So the next thing that really comes to the importance of such, and you had asked, I talked to you about data sharing yesterday. The EPA, the City of Flint, and DEQ have requested the data that you have regarding the low chlorine levels. Has that been sent to them yet? That was the data sharing I was referring to?

DR. MCELMURRY: It has not, we did not have price speci--we do not have spatial attributes attached to that data. When we do get the spatial attributes finally tied to the data, we will have to go through somewhat of the identification process, so that they don't give specific addresses per our IRB.

DR. WELLS: Am I being to harsh, or should I just keep going?

MS. CALLO: Just keep going.

DR. WELLS: Yeah? Okay, so we're having--this is probably the meat. I kind of, you know, I feel pretty good

as much as we went over the study protocols with you this summer regarding how important we all feel about the randomized control status. However, what really brought up with the press release this week is that there was a reference to under-chlorination to a population in the community. And then questions were, of course, being brought to me by your group as to what recommendations I would have for those groups.

Unfortunately, this becomes a highly complicated water engineering issue which I would hope would--of--had some information from your group to help us in that decision but also having to work with DEQ and EPA to do that. Your program--this project is clearly at, by virtue of how it's developed, has the ability to identify, either individual or public health risks on any given day.

Now, what probably--you all have done this type of study before, Shawn. I've done other studies that have shown environmental issues, but as far as we were kind of fine tooth combing this protocol this summer, what is concerning is that there does not seem to be a process in place, and you'll here on the agenda that I wonder if this would be a potential contract addendum. Because there is a public health threat that could be identified in your study, whether it is microbial growth, whether it is low chlorine levels, there must be a way that you immediately are able to

not only, once you identify that in your data, that you were able to immediately--immediately identify the households impacted so that information may be relayed immediately to the city, DEQ, EPA, and the public health authorities.

And I---my co--EPA mentioned to me last evening that they've understood that you've had this identification of low chlorine levels in your households for over two weeks. They've been waiting for the data since yesterday morning or the night before. This is, I think, a particularly problematic ethical issue regarding, you know, having data, then reporting about it in the public but then unable to provide us the information to respond. And so I do think that this is the most important issue we need to resolve today as to how you all are going to be able to get that data to the city, which should have occurred probably over 24 hours ago, if not two weeks ago from my EPA understanding.

What are your thoughts on this, because I don't see how we can move forward without that type of safety net in place.

DR. MCELMURRY: Thank you, Eden. We do share your concern about these values. Part of the reason why we shared these results immediately before even analyzing them in the level of detail that you're requesting, I shared those with Mark Dernal (ph) originally when I started

recognizing the data coming back at those levels, and he did not raise any alarms to me that that was a concern to him. He did say he looked at the data, he never said, no, this has to--you know, reported--want anything. So, you know, I do--I am concerned about the values, that's why I reported it as soon as I realized that we had this problem. I'm reporting to real time (??). The protocols we're using, he identifies the data and it takes time to push that back. I have devoted two people now, taking them off other things and putting them--prioritized, getting this part down.

DR. WELLS: Slowing us way down.

DR. MCELMURRY: With that there's a lot of checking the addresses, you know, and those kinds of things to make sure we're accurately understanding the problem. And that's what we are doing now. And as soon as we have that data, I will be sharing it with all.

DR. WELLS: Okay. I don't know, that may not be sufficient, I'm going to sto--I know I've been talking as though as I probably had way too much caffeine. But let me--Sarah, do you want to weigh in on this?

MS. CALLO: So Shawn, I'm trying to understand. So you collect these samples in. You get a result, it's--de-identified or separated from the address at that point and then the testing occurs and then a result comes back and you can see there's an issue, but you don't have a very

quick way of relating that back to the address that the result came from? Is that the issue?

DR. MCELMURRY: Exactly. Because we--through our consent process that information is kept separately. It's not that we can't get it back, but we have separate barcodes for these things. On the barcodes there's no way for me to look at the barcode and tie it to another sheet without doing it in the database. And so the field sheets that are handwritten have to be manually entered into the database on both sides of that before we can start tying these together. And so that's what we are building on both sides.

(Ms. Wells and others are speaking to each other while he is speaking)

I can tell you already that we have all the addresses, at least up until I don't know, Monday or something like that, last Friday probably, Saturday probably. All of these addresses in the database they're checking them because there are errors. I've known of one particularly that was, you know, 2200 and it should have been 22--2202, and it should have been 2022, and that creates a huge difference in location. So those kinds of things take time to ferret out.

And then on the flip side we also have our field data sheets that come in. They are spot checked when they're brought in, but they do not--they have not been

entered into the database until we started seeing these generally, you know, these system we were weaving. And so that's why--that's why this has kind of--I'm feeding this in pieces because I'm giving you a real time understanding of the situation. It's not that I have a better understanding, it's what I'm relaying to you.

MS. CALLO: Um hm.

MR. MCELMURRY: And so when we started realizing this we're devoting resources to that, but to be quite honest we don't have the resources to be able to do that in any faster fashion than we're currently doing now.

MS. CALLO: So have you thought about using like scan-tron (ph) forms and things like that so that you're not having to do hand entry?

DR. MCELMURRY: So we have scan-tron forms for our surveys, but for field data when you're recording, you know, chlorine levels, that is a handwritten number.

DR. WELLS: But you've only done 78 households right now, right?

DR. MCELMURRY: What's that?

DR. WELLS: You've only done 78 households at this time, is that right?

DR. MCELMURRY: No, we have--I mean, I think--I don’t know what the total number is right now, it’s over 100 households that we’ve sampled.

DR. WELLS: Okay. That's good to know. No, and we're trying--and I guess here's the issue as I realize that you--you know, but--but if there--here is the concern, I guess, that I was really struggling with in the last 4 to 8 hours. There are attorneys ask us what is going on with the response to lower chlorine residuals in households. Now, it turns out EPA and DEQ say look the chlorine residuals themselves don't automatically require a boil water alert. Thank goodness they were able to respond to that question of mine.

MR. MCELMURRY: Yes.

DR. WELLS: However, it does require an immediate response by the city and by the EPA and DEQ to immediately go assess those homes. So if that's not happening, what we have is an ethical issue of people who have knowledge and, in fact, frankly reported knowledge of potential health harm into the public, but without the ability to identify where that harm is. So I think that there's going to have to be a way to better identify those households at risk. I am not--and I guess other than--we do a lot of field studies and I have never heard of it being that difficult to get back to the home that we're actually working with. I mean, this is what we do in public health, but I would have to refer you to other folks that are actually on the ground that are more experts than I, 'cause I don't know what that answer would

be at the moment.

Do you, Sarah? Other than scan-trons?

MS. CALLO: (No audible response)

DR. MCELMURRY: So, so--Eden, if I could suggest something here. I would be happy to have you and Sarah and anyone else who is interested walk through the operation that we have set up in the Broome Center to see all the processes that we do. And we intentionally put in barriers to this to prevent actional release of identifiable information. Unfortunately those barriers also create--there is when we try to put it back together. In other settings I have had far less controls on some of these things, it's a lot easier for me to say, okay, I'm going to sit down today and I'm going to pull this all together. Unfortunately that is not this situation, and, you know, with more time, you know, maybe they could come up with a more streamlined process, but we're really strung on the number of people that we can devote to this. There's just not--I mean--

DR. WELLS: So you--so the question we have here is apparently you have done this type of research before where your findings can have public health implications, but in previous studies you've been able to address, you know, identifying a public health threat because you could tie things back to the household.

But in this--in this study protocol you cannot.

DR. MCELMURRY: So the answer to that is I have done this kind of thing, we've measured chlorine before and we found it low. And I reported that back to the EPA and DEQ. In, you know, about the same time that I'm doing now. You know, I have not had the same level of urgency from the DEQ and the EPA regarding the data I'm showing. I'm trying to identify issues that they should be looking closer at with the system. Apparently they tell me that there are-- the chlorine levels in their system are being maintained, which is of course good, but there might be other underlying problems that we haven't been able to verify and that's why we're trying to get this done, to be able to have a better understanding of that.

DR. WELLS: Yeah, I think the urgency came when there were requests from your group for me to try to advise on a public health response. I know that your team doesn't want to make public health recommendations, and we don't want you to, but this is precisely the issue. We cannot make a public health response determination without the ability to test these sites. So I'm--

DR. MCELMURRY: So, what--

DR. WELLS: --I think this is important.

DR. MCELMURRY: I'm sorry. I'm sorry for interrupting.

DR. WELLS: Go ahead.

DR. MCELMURRY: One of your items on this is public health versus individual--public health versus individual health threats and we're unsure if this is a public health threat or an individual health threat because we don't have enough information. Okay? So that's why, you know, any time we--if we were to find something that we think is a public health threat, we will, of course, relay that information as fast as we can. The same thing goes with individual. So I understand the position you guys are in and we're trying to get to you as fast as we can with prioritizing and, you know, I wish it could be faster, but given--given what we have, we just--

DR. WELLS: For the sake of the agenda, for--I'll take that under advisement, but I am--that could be an issue. I guess my co--I just could imagine, maybe you find something--somebody's got some horrendous I don't know what in their water and that you--that this perhaps as one of those things where we all go duh, in the middle of a study, but this has to be addressed to preserve the safety of the people being studied.

DR. MCELMURRY: You know, maybe in the interest of time, I understand this is a really critical issue, but let me make a suggestion. One thing we may be able to do is change our protocol so that any time somebody comes in with

a chlorine level below some threshold, .1 or .2, that, you know, they immediately somehow bypass some of the system and so that we can have, you know, more immediate response. But the other problems--so--I don't--I don't know--that's--

DR. WELLS: That's something to think about, yeah.

DR. MCELMURRY: --something--have to talk in more detail.

DR. WELLS: I think it's under the title potential contract addendum essentially. Because what it brought really to light is we had attorneys at our level basically wanting information that we were trying to get from your group as to what type of threat this constituted and it sounds like even as of today that is actually--

DR. MCELMURRY: We don't know.

DR. WELLS: --still unclear. And so--

DR. MCELMURRY: Yeah.

DR. WELLS: --this is--and so you can imagine that this has put us into a bit of a bind. All right. So that's okay. And then, you know, again I think that leads into number three which is the immediate identification of an affected household. So there may need to be a screening step or something that involves the safety of the wa--of the, you know, this is to protect public safety essentially that they--there are individual and public health risks for any study that is looking at issues that may affect health,

obviously, within the water system.

All right--

DR. MCELMURRY: So, let me--can I add to that real quick, Eden, if you don't mind?

DR. WELLS: No, absolutely.

DR. MCELMURRY: What would help us is to understand--in the inner protocol we did have with the Bilden (ph) investigation side of things, we did have a threshold in which we would report to you guys as a (unintelligible). And that's in part of our consent process with the individuals. We do not have that in the other protocols in the household survey. So that's something we all missed. So as a result of that, I need to ask individuals to report--to allow me to report their individual address back to you.

DR. WELLS: I think so, yeah.

DR. MCELMURRY: Protocol change? I'm not against that, I just--I think we need to think about that and do that.

DR. WELLS: And think about it while preserving this obviously. So, you know, here's the issue, folks, and just so we're all clear and I know I started off just wanted to get my word in because I've been concerned that I think sometimes people think we in public health really don't know a whole bunch of stuff, but, you know, we clearly want an

independent research group. We don't care how much Legionella you find, I mean, whether you're finding it, you know, in the street puddles, we're okay with that. I'm totally okay with that. This is not to limit the work that you're doing or to even change the findings. What we do need to make sure that we're not getting stuck in a situation where, you know, this is not even to do with a protective order, is that first, that the internal and external validity of the study is not compromised; second, that the ethical issues and conc--you know, requirements are always maintained. And the third is that the public health and safety is always foremost. And so that's really the issue. So if it means a change in protocol, it would--we would obviously want that to do be done, that would not compromise your study's integrity.

But it is of enough concern that I think--I feel that I was put in an untenable situation, I still remain in an untenable situation, and it sounds like that we still haven't been able to get the data going. So I think if we can think about that over the weekend, we'll be glad to work with you with any thoughts on a potential contract addendum. Okay?

DR. MCELMURRY: Yeah. And let me just say this. We do not think that--we appreciate your experience, everyone there. We understand you guys are a dearth of

experience, we in no way take that for granted, and so, you know, please, this has been said multiple times and I'm sorry that some of you may have gotten the impression that we do not appreciate your backgrounds and your expertise because we do realize it, and we consider it extremely valuable, that's one of the reasons why we've had--at least early on we had a back and forth relationship on communication.

DR. WELLS: Right.

DR. MCELMURRY: So I would like to say in the interest of time one of my suggestions on this is we did meet regularly, and part of this might be attributed to the PO, you know, that was put in place.

DR. WELLS: Yeah.

DR. MCELMURRY: I think we need to do that. I think, obviously, because of the protective order, we should even with Genessee County help––

DR. WELLS: Sure.

DR. MCELMURRY: I think we--you might keep that, you know, we need to get to a standing meeting to have communication more frequent, I think that will ease a lot of these––

DR. WELLS: Yeah, and I think--and as you said, even as much as all of us went through the protocols, because this was so complicated, I know this is probably one

of the more complicated multi-stratified protocols that we've--that I've had experience working with, and certainly with you all this summer, that it certainly didn't occur to me until we got into this situation this week that that type of notification or feedback loop has to be more immediate.

All right. So we'll do that and certainly we'll broach the possibility of following meetings without upsetting our prosecutors.

Just to move in, Item B I think has been adequately been addressed by Ian Horste, who is here today, and I appreciate your confirmation that you've addressed this with your IRB and that you're putting in additional safety measures for protection of any data that's released by our department. I don't think we need to go anymore unless, Sarah, did you have anything?

MS. CALLO: So one thing I did not say in my email, Paul, you know, I figured you would be reporting to whatever portions of your university you have to report breaches to, but I did want to make sure that you were aware that reporting-–

DR. MCELMURRY: Sarah--

MS. CALLO: Yeah.

DR. MCELMURRY: This is Shawn. And first let me apologize on behalf of our entire team and, you know, that is not something that obviously was an accident and it's not

something that we ever wanted to happen and we will try our best to never let that happen. And that would be why we'll be meeting after it to make sure we review the DUA, review our IRBs and the Scott (ph) positional measure that we can put in, I'm happy to update you on that.

Let me just say this, that I appreciate you email identifying this, and, you know, I really appreciate all the immediate response to your follow-up with that last night and this morning. This morning our IRB office did receive notification, multiple notifications from us, including a formal--you know, the formal protocol form submitted and so our IRB office is fully aware of the situation and it will be reviewed--I'm not exactly sure who's going to review it, but it goes to a panel or a board or something like that. So there will be follow-up there and I'm happy to connect our IRB to Ian and make sure that's taken care of. But we will resolve it, this is unacceptable from our standpoint and, you know, it's not going to happen again.

MS. CALLO: And I appreciate that. It's not the first project I have worked with that has had a breach and the importance is that breaches are addressed when they occur and that there is an immediate response as well as a response, a preventative response. So both remediation and prevention need to occur after a breach.

Here at the department when we have something like

this happen, if it's an IRB covered project, of course we report to IRB but we also report to our privacy area as well, even if we--we're not sure it's a breach or not, so--and all of those things here have to occur within 24 hours.

So since I didn't know your Wayne State procedures, I did not want to, you know, appear to be instructing you on your own, but I also wanted to be sure that that had been thought of at your end and covered.

DR. MCELMURRY: Yeah, it has. And I'm happy, you know, if there's any questions, please, I'm sure Paula and--any of us would be happy to discuss and come up with the both immediate and, you know, long term actions.

MS. CALLO: Well, I think the data use agreement is fairly well written in English. A lot of data use agreements it's all this party to that party, blah blah blah, and this one is fairly plain English. So I think, you know, just routinely looking at that, so that you're not forced to operate from assumptions would be a good idea. I know, you know, like something you can check off and be done with.

DR. KILGORE: This is Paul Kilgore. I just want to say you're absolutely right. And I wanted to say thank you very much, Sarah, as well. And also echo all the tenements that Shawn expressed, well put, and we thank you very much.

MS. CALLO: Okay. Well, there is a couple of things I did want to reiterate about the data use agreement, just so that, since we've got this moment we can do that. When you look through it, there's an Item Number 7, towards the back. It's in Section 2, "Agreement Conditions".

DR. WELLS: Page Six of Eight.

MS. CALLO: Yeah, Page Six of Eight, of the executed version. And there there's a piece about providing MDHHS with at least 30 days notice to review and provide comments on papers, publications and presentations that data recipient plan to submit for publication for presentation. That's one of those ones where that's easy to get missed, I know from other experiences. I think, you know, again, it's--it would be particularly, if we're talking about a contract amendment or something, it would be a good idea to look at Item 2 under Section 2, the same page, in terms of who your team members are, you know, in case like you've added a PI or something like that, somebody needs to be added to the data use agreement so that you're being proactive in approaching the department about that ahead of time.

And then, I mean, quite frankly, when I saw the email come through, I mean, this was the first thing I reached for and I was just reading through on page one, you know, sections one and two, about what was our intention

about what would get shared. Because, again, the purpose of this is not in any way to slow down the research or be punitive or anything like that, it's not what--you know, not what I'm interested in being or doing, it is to make sure that we are protecting the public's trust in allowing us to use this data. So--okay, so--

DR. KILGORE: Well, said. Thank you for pointing it out.

MS. CALLO: If you'd take a look at those too, I would very much appreciate that. And, Paul, thank you for the speed with which you got your email out to people and your responsiveness there, that was very much appreciated.

DR. WELLS: Yeah, I agree, that was fast and that was good.

Just a couple things and I know you all--it's already past, but I think it's important. We did note that with that email, Paul, that you had designated Mr. Valichek (ph) a co-principal investigator.

Carrie, are you on the line by any chance?

MS. WAGGONER: Yes, I'm here.

DR. WELLS: Okay. This was just a question we had regarding--I don't know, the key personnel were already identified in our contract, and so I'm not certain, while you may have subcontracted with Mr. Valichek (ph), I'm not so certain that he is a key personnel, so I don't think you

can make him a co-PI. I think it would have to be a subcontractor. I'm looking at my con--I've got three contract people in front of me here. Okay, they're nodding. So your designation of a co-PI probably would not be accepted and should probably have come through us first. You can subcontract, but that person could not be made a key personnel unless that is brought to our contract people.

DR. KILGORE: Okay. And with Shawn what we will do is go back to our--Mike Anderson and Mike Moffer (ph), the grants and contracts folks and review that with them so they're aware of what your policies are as well.

DR. WELLS: Okay, thanks. And there is some specific language that Farah has that we can forward to you if need be.

DR. MCELMURRY: I appreciate--I missed that, and also when we do subcontracts oftentimes at the other universities, and I realize FACHEP is not a university, but other universities they will, the people at the university that are awarded the subcontract will call themselves a PI for the university contract. So that's probably, you know, we'll have to make it right and we'll review all of our subs to make sure that it aligns with state policy.

DR. WELLS: Yeah, I don't think it's just state, I know I've done a number of subcontracts over at our university and the key personnel are usually identified

prior to the implementation of the study. So when you're subcontracting out after the study has been done, I'm not so certain you can just add key personnel on that in the middle of the game. So I just wanted to make a point if there's any updates or changes or additions to key personnel, let our staff--if anything, you know, Ian, myself, really--Sarah, us three, we'll make sure we're working with our contract people who are here with us today.

That's not to say I don't think the contract should be there or anything, but it starts changing or altering the study's structure as it was submitted. Okay?

DR. MCELMURRY: Appreciate that, Eden.

DR. WELLS: Yeah. And so that's--I actually, and again I want to reiterate, the press release, I really--actually, to tell you the truth, I had no concerns with until our attorneys asked a question. And then the attorneys asked a question, I went, oh, you know, again, slap on the forehead, let me call my folks over at FACHEP to help me answer this question. And I know that there will be other press releases, because we do want your findings. I do want--if there is information that needs to get out there, folks, and Matt, you were wonderful sharing it, as you've done with all the stakeholders, and, in fact, that totally complies with the data use and all of that, that you really engage to stakeholders.

I do ask, when a press release goes out, one of your team, technical people or whoever--whoever the person's expertise best ties to what the content is in the press release, be available. You need to understand, I am calling you guys. It is not to say hello. I'd love to, but it's usually because we've got something burning. And when I've got the assistant attorney general waiting on another line, I would have appreciated a response, and the only timely response I got was from Matt Seeger--bless you, Matt, thank you, I know you were you on another call, but that was precisely--I needed technical people. And then it took me--and listen, I've got about as many meetings as you guys do. Maybe or maybe they're not as important as your work, I don't know, but I spent the afternoon then finding--being able to get this information from EPA and DEQ, which actually doesn't make me feel real comfortable because I actually want the scientific input from the actual independent authority that generated the data.

So if we could just be sure in the future, be available. You certainly were prior to the release of the press release, but then you all disappeared, except Matt. So that is a personal plea. Go ahead.

DR. MCELMURRY: This is Shawn, and let me personally apologize--

(Dr. Wells is speaking internally while Dr.

McElmurry is speaking)

DR. WELLS: That there was nobody to question-- yeah, they did about the contents.

DR. MCELMURRY: --were not paying attention to your calls, I certainly prioritize everything you do. You know, part--I've had times when it's been difficult for me to understand based on the protective order what I can do, but certainly I know there were times on Tuesday that I was just tied up with things and could not answer my phone. So, like teaching in a class I can't leave my phone on when I'm teaching. So there's certain things I will try to make it real clear, you know, when I'm available and whatnot.

(Speaking in room while Dr. McElmurry is speaking)

DR. MCELMURRY: But--I just--my apology and please understand that I, you know, I really do try to respond to you as fast as possible.

DR. WELLS: Yeah--

DR. SEEGER: This is Matt.

DR. WELLS: Sure, Matt.

DR. SEEGER: If I could just add, you know, there some reasons, strategic reasons why we did the press release when we did. But should we do another press release in the future, I think we need to have more coordination with you folks before the press release goes out, with your communications staff. You know, I've worked very close with

Angela, I'll keep working with her--

DR. WELLS: Yeah.

DR. SEEGER: --and Jennifer. But I think there are some things--I mean, we could share some points with you, some of the talking points that we're thinking about, some of our strategy, I know that came out in the conversation but I think had we shared that with you more fully in advance you might have understood a little bit more clearly what we were trying to achieve with putting the press release out when we did.

DR. WELLS: No, I understood the strategy of that, but I think maybe if you know then it might be at a time hopefully that there's not a teaching of a class. Or I would ask, I think if you all--I mean, if you were the only person to answer that, or if you have a study manager, I put that actually above, study manager or data coordinator who can answer these questions in addition to, or figure out a way to state, you know, I'm teaching for an hour I'll get back to you during break or something.

But I have also been caught with calls from higher ups when I'm in the middle of teaching. I have actually learned to actually have to stop at times to step out. I have certainly had to step out of at least four different meetings on that afternoon because we have to prioritize the public health threat. And so that's just something to think

about, that usually when we're doing that is because we have a particular health issue that may be at hand. Okay?

So just thinking about that, we'll work together on that. Okay?

DR. SEEGER: Thank you.

DR. WELLS: Yeah. And I think that's it, other than I was just going--we can talk about this another time. There is the--Sarah already brought up the IRB and privacy officer reporting issues. Just that we're going to be getting into monthly and quarterly reports as well, and thinking about what kinds of formats those should be in. But we'll table that.

I appreciate this, I just--the reason why I was sort of waxed wroth at the beginning is that there is really--there's been a number of meetings all together, or whether it's in through emails that may or may not be as--I don't think--personally I think we all respect each other really well, but I think sometimes there is perhaps not an awareness that our lives here, we are on triggers, and it's not just because of Flint, but we are--our careers, our lives, our passions are built around the immediate need to respond to an individual or public health threat.

Just like, I know Mark Zervos, you get to call somebody's, you know, your guy's going septic and you're running down the hall. You know, it's just that's our

trigger response. And so there's been some feeling that perhaps while academia is, you know, collecting all this data and may be able to sort of talk about this in the press--and, again, I'm not faulting you on the press release, but the impression was is oh, well, you know, MDHHS will go figure out what to do about this, and I--and so I just want, I plead that, you know, public health, to us in our world reigns supreme, and we will--we will continue to advocate for your role as an independent, as independent as can be, but remember we're funding you, and our IRB is with you, but we want you to be as independent, we want you to find anything with the system that had anything to do with the Legionella outbreaks would be great, but to please understand our passion and some of our knowledge when it comes to trying to do these studies in the public sector. All right?

DR. MCELMURRY: Thank you, Eden.

DR. SEEGER: Yeah, thank you.

DR. MCELMURRY: Thanks a lot for your time and making this work. And let's maybe next week we can have a longer discussion of some of these things and really get down to business on some of these critical issues.

DR. WELLS: Yeah. We can work together on this potential addendum, okay?

DR. MCELMURRY: Thanks a lot.

DR. WELLS: Is there any other words for the wise? Our contract people have been quiet but they've been nodding a lot and helping with the--Carrie, any thoughts on your end?

MS. WAGGONER: No, I don't have anything to add.

DR. WELLS: Okay. For you guys, again, thank you. You are great partners, but we felt this was really important and I appreciate just being able to get this all out there so we can all plan accordingly and get some things resolved next week. Okay?

(Many thank you's and goodbyes)

(Phone all hang up)

MS. HANLEY: Wow, that's concerning. I mean--

DR. WELLS: He still hasn't gotten that household data.

MS. HANLEY: What the heck? Seriously. Those of us here around the table could be doing what--it doesn't take a rocket scientist.

DR. WELLS: No, it doesn't.

MS. HANLEY: Really? Hand entering?

DR. WELLS: Yeah.

MS. HANLEY: I can't believe it. And it's like--I mean, what do you need for it to be a public health emergency? I don't get it. I mean, we talked about, not just Ebola, but the Zika and whatever else. I mean, there

aren’t a lot of people who have it, but there’s the threat that it could spread, right? And so I just don’t understand why it is that they’re slicing hairs like that, and they’re sitting there spending the time to make these determinations.

MS. CALLO: Right, when they’re telling us that, oh, it’s my ethics, my engineering code of ethics, remember that? Anyway, at one point I got this big speech they have this engineering--(fades out and recording stops)

S-T-A-T-E-M-E-N-T
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