Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP)

From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP)
Sent: Monday, March 30, 2020 6:39 PM
To: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP)
Subject: RE: Human Subjects Review-specimen testing protocol

Erin, thank you for submitting a research determination request for the project titled, "Investigation of pregnant and peripartum women infected with COVID-19 and infants born to infected women". The purpose of this investigation is to gather data from the testing of specimens during pregnancy, delivery, and peripartum to inform the decisions and actions of CDC related to COVID-19 infection control strategies for pregnant women, peripartum women, and neonates. CDC will collect and test pregnancy-related, infant-related, and breast milk specimens to describe viral shedding in pregnant and peripartum women who are infected with the virus that causes COVID-19.

The specimens tested will provide information that will be used to identify and characterize risk of transmission in pregnant and peripartum women to their fetuses and/or neonates, inform infection control measures, assist CDC in making health care recommendations, and provide a direct link to decision making and actions to be taken by public health authorities and health care providers.

This project will provide timely situational awareness during the course of an event that threatens the public health. As such, it meets the requirements of public health surveillance (not research) as defined in 45 CFR 46.102(*l*)(2).

The Paperwork Reduction Act applies to this project since data will be collected using a case reporting data form and supplemental pregnancy module. The case reporting data form is currently approved under a GenIC submitted under the Emergency Epidemic Investigations generic clearance (OMB Control No. 0920-1011, Expiration Date: 04/24/2020). If data collection will end after April 24th, the task force can submit a new GenIC under the Emergency Epidemic Investigations generic clearance to obtain a 90-day OMB PRA clearance for data collection.

Let me know if you have any questions.

Thanks,
Alisha

From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Sent: Monday, March 30, 2020 2:16 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Cc: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Alisha,
Attached is the protocol with a highlighted section added about getting the Case Reporting Form data and the Supplemental Pregnancy Module data.

Let me know if you need more information. I have also attached a near final version of the pregnancy module in case you want to see what it will include.

Thanks!
Erin

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From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Sent: Monday, March 30, 2020 1:16 PM
To: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Yes, that sounds good.

So, also want to make you aware that there are PRA implications with the addition of the case reporting form completion. There's OMB PRA clearance right now for the case reporting form as part of a GenIC submitted under the Emergency Epidemic Investigations generic clearance, but it expires on April 24th. Not sure if your data collections will be completed by April 24th. I'm sure we could roll this project into whatever OMB PRA clearance we'll use to continue with the epi investigations related to the response after April 24th.

From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Sent: Monday, March 30, 2020 12:56 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Subject: FW: Human Subjects Review-specimen testing protocol

Hi Alisha,
I checked in with a few others.
We are thinking that adding a little language to the protocol asking hospital staff (most specimens will be collected during birth hospitalization) to complete the approved Case Reporting Form https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf and Pregnancy Supplement (which should be live today) would be a good addition.

Would you like me to add that to the protocol and resend so you can review the prosed addition?
Thank you,
Erin

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From: Ellington, Sascha R. (CDC/DDNID/NCCDPHP/DRH) <frk5@cdc.gov>
Sent: Monday, March 30, 2020 10:21 AM
To: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>; Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Erin,

Yes, I think that makes sense. Maybe we could include some instructions about completing the supplemental form if it has not already been completed by the jurisdiction. Also, perhaps add that we would want to link to the general CRF (https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf) since the pregnancy supplement was not meant to stand alone.

Thanks,
Sascha

Sascha Ellington, PhD, MSPH, CPH
Lead, Emergency Preparedness and Response Team
Field Support Branch
Division of Reproductive Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Email: sellington@cdc.gov
Phone: 770-488-6037
CDC Reproductive Health in Emergency Preparedness and Response

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From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Sent: Monday, March 30, 2020 9:58 AM
To: Ellington, Sascha R. (CDC/DDNID/NCCDPHP/DRH) <frk5@cdc.gov>; Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>
Subject: FW: Human Subjects Review-specimen testing protocol

Sascha and Cria,
Alisha is asking that if we wanted to include the Pregnancy Supplement to the CRF as additional data to go along with the specimens who would fill out the case reporting form?

As you said on the call this morning Sascha perhaps we add a line about having hospital staff fill out the Pregnancy Module during the hospital stay and then the Pregnancy Supplement is sent with the specimens. I do think having some of the epi data with the specimens would be helpful.

Thoughts/suggestions?
Erin

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From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Sent: Monday, March 30, 2020 9:36 AM
To: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Erin,

Sorry for the delay in my response. I did take a little time away from the computer yesterday 😊 Hope you had a good weekend.

Just want to make sure I'm understanding this correctly. So you're relying on obtaining the epidemiological data for these cases from what the state has reported on the case reporting forms?

If you incorporate the case report form into this investigation, would the participant complete it?

From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Sent: Saturday, March 28, 2020 9:58 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Alisha,
I just had a thought-so if the specimen testing protocol is considered public health surveillance and our pregnancy supplement for the case reporting form is also public health surveillance-can we combine the two?

Have a great night and I hope you get some time away from the computer!
Erin

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From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP)
Sent: Saturday, March 28, 2020 9:47 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Alisha,
The plan is for the women to just provide specimens.
We went back and forth on collecting epidemiological data from the women.

Completely separate from the specimen testing protocol we created and have implemented a supplemental pregnancy module to go along with the COVID-19 case reporting form that the states are using. If the pregnancy box on the case reporting form is selected then we are hopeful state will collect the additional pregnancy data. So we are planning to get some epidemiological data from the pregnant cases that would be separate from the specimen testing.

Any ideas you think we should consider?
Thank you-Erin

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From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Sent: Saturday, March 28, 2020 8:59 PM
To: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Erin,

This is much clearer and makes it easier to justify as a public health surveillance activity. Will the participants complete any questionnaires or just provide the specimens?

From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Sent: Saturday, March 28, 2020 1:57 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Awesome thanks!

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From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Sent: Saturday, March 28, 2020 1:53 PM
To: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Cc: CDC IMS 2019 NCOV Response At Risk Medical Conditions <eocevent346@cdc.gov>; Galang, Romeo Regi (CDC/DDNID/NCCDPHP/DRH) <ydh0@cdc.gov>; Tromble, Erin (CDC/DDID/NCHHSTP/DSTDP) <lzn6@cdc.gov>; Ellington, Sascha R. (CDC/DDNID/NCCDPHP/DRH) <frk5@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Thanks Erin! I will take a look and get back to you later today.

From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Sent: Saturday, March 28, 2020 1:48 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Cc: CDC IMS 2019 NCOV Response At Risk Medical Conditions <eocevent346@cdc.gov>; Galang, Romeo Regi (CDC/DDNID/NCCDPHP/DRH) <ydh0@cdc.gov>; Tromble, Erin (CDC/DDID/NCHHSTP/DSTDP) <lzn6@cdc.gov>; Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>; Ellington, Sascha R. (CDC/DDNID/NCCDPHP/DRH) <frk5@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Happy Saturday Alisha,
I'm writing to send back the pregnancy specimen testing protocol. I'm sending a clean version because the Team made many changes based on your comments/suggested re-frame. If you would like to see a track changes version please just let me know.

Also if you would like to discuss any questions you might have we are happy to jump on the phone this week (if phone vs. email is easier for you).
Thank you for your time and assistance!

Erin

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From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Sent: Friday, March 20, 2020 8:47 AM
To: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Cc: CDC IMS 2019 NCOV Response At Risk Maternal Infant Child Health <eocevent346@cdc.gov>; Galang, Romeo Regi (CDC/DDNID/NCCDPHP/DRH) <ydh0@cdc.gov>; Boundy, Ellen (CDC/DDPHSIS/CGH/DPDM) <lwz9@cdc.gov>; Tromble, Erin (CDC/DDID/NCHHSTP/DSTDP) <lzn6@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Erin and team,

Thanks for your time yesterday to discuss the proposed protocol, titled "Investigation of Pregnant and Postpartum Women Infected with COVID-19 and Infants Born to Infected Women". As discussed, attached are my comments within the protocol. I encourage you to strengthen the language within it to highlight the intent – how this investigation will directly inform public health decision making or actions. Let me know if you have questions after reviewing the comments.

Thanks,
Alisha

From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Sent: Wednesday, March 18, 2020 11:31 AM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Cc: CDC IMS 2019 NCOV Response At Risk Maternal Infant Child Health <eocevent346@cdc.gov>; Galang, Romeo Regi (CDC/DDNID/NCCDPHP/DRH) <ydh0@cdc.gov>; Boundy, Ellen (CDC/DDPHSIS/CGH/DPDM) <lwz9@cdc.gov>; Tromble, Erin (CDC/DDID/NCHHSTP/DSTDP) <lzn6@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Alisha,
Thank you for your questions. I worked with our Maternal and Child Health SMEs on our responses:

What is the specific public health action that will be undertaken as a result of this investigation?
Results of this investigation will assist CDC in making guidance/recommendations regarding care for pregnant women who are infected with the virus that causes COVID-19. Examples of guidance/recommendations could include whether or not to initiate or continue breastfeeding, inform infection prevention and control recommendations around the time of delivery, both for prevention of infection to the newborn, healthy caregivers, and to healthcare personnel, and recommended delivery mode (vaginal verses Cesarean section). Right now, there is not enough information on COVID-19 in pregnancy to adequately inform public health action for pregnant women and their babies.

How will participants be recruited for this investigation? Are there specific hospitals from which participants will be recruited?
Any hospital or hospital system that provides care to pregnant women could be included. There might be specific health systems with particular interest in COVID-19 during pregnancy that would be interested and willing to participate. Information about the protocol could be provided to professional organizations such as the American College of

Obstetricians and Gynecologists (ACOG) to make their members aware that specimens could be considered for submission to CDC if they have pregnant patients diagnosed with COVID-19.

Will any other data be collected from participants beyond the consent form?
The Case Reporting Form for COVID-19 surveillance has a check box for pregnancy. The At-Risk Task Force has created a Pregnancy Supplement that can be filled out for pregnant cases (when the Case Reporting Form [CRF] box is checked Yes for Pregnancy). We were not planning to collect any additional epidemiological data beyond what is captured in the Case Reporting Form and Pregnancy Supplement.

We believe the data collected through the CRF and pregnancy module are already de-identified (and approved for public health surveillance purposes).

Let us know if we should include verbiage about collecting the public health surveillance data in our protocol.

Thank you and please let us know if you have any other questions.
Erin

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From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Sent: Monday, March 16, 2020 8:54 PM
To: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Cc: Vagi, Sara J. (CDC/DDPHSIS/CPR/DEO) <hgq2@cdc.gov>
Subject: RE: Human Subjects Review-specimen testing protocol

Hi Erin,

Thanks for submitting the protocol for your proposed investigation.

I have a few follow-up questions after reviewing the protocol. What is the specific public health action that will be undertaken as a result of this investigation?

How will participants be recruited for this investigation? Are there specific hospitals from which participants will be recruited?

Will any other data be collected from participants beyond the consent form?

Thanks,
Alisha

From: Vagi, Sara J. (CDC/DDPHSIS/CPR/DEO) <hgq2@cdc.gov>
Sent: Monday, March 16, 2020 4:21 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Cc: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Subject: Fwd: Human Subjects Review-specimen testing protocol

Hi Erin,

I was serving in this role but I have been deployed. I've cc'd Alisha Etheredge who is serving in that role now.

Thanks,

Sara J. Vagi, Ph.D.
CDR, USPHS
Associate Director for Science
Division of Emergency Operations
Center for Preparedness and Response

From: Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP) <ige7@cdc.gov>
Sent: Monday, March 16, 2020 11:57 AM
To: Vagi, Sara J. (CDC/DDPHSIS/CPR/DEO)
Cc: Ellington, Sascha R. (CDC/DDNID/NCCDPHP/DRH); CDC IMS 2019 NCOV Response At Risk Maternal Infant Child Health; Sauber-Schatz, Erin K. (CDC/DDNID/NCIPC/DIP)
Subject: Human Subjects Review-specimen testing protocol

Hi CDR Vagi,
I'm writing to request human subjects review of a specimen testing protocol for an investigation titled: 'Investigation of pregnant and postpartum women infected with COVID-19 and infants born to infected women'.

Please let me know if you need any other information.
Thank you,
CDR Erin Sauber-Schatz

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