

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

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**From:** Gieraltowski, Laura (CDC/DDID/NCEZID/DFWED)  
**Sent:** Monday, April 20, 2020 1:05 PM  
**To:** Gieraltowski, Laura (CDC/DDID/NCEZID/DFWED)  
**Subject:** FW: Covid seroepi investigation protocol

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**From:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Sent:** Tuesday, March 24, 2020 8:38 AM  
**To:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Subject:** RE: Covid seroepi investigation protocol

Holly,

Thank you for submitting a research determination request for the project titled, "Investigation of SARS-CoV-2 Seroprevalence and Factors Associated with Seropositivity in a Community Setting". The purpose of this project is to (1) determine the extent of infection in communities as determined by overall SARS-CoV-2 seroprevalence; and (2) determine factors associated with SARS-CoV-2 seropositivity among persons residing in areas with evidence of community transmission. The extent of transmission in communities will be investigated to inform decisions about prevention and control strategies and community mitigation interventions in the U.S. response to COVID-19. As this activity involves the investigation of community transmission by a public health authority to provide timely situational awareness and priority setting during the course of an event, it is consistent with **non-research public health surveillance**. Once the volume of blood that will be collected is determined, I strongly encourage this information be added to the consent and assent form.

This activity involves a CDC-led and conducted data collection from at least 210 households; therefore, the **Paperwork Reduction Act applies**. A GenIC will be prepared and submitted under the Emergency Epidemic Investigations (EEI) generic clearance (OMB Control No. 0920-1011, expiration date: 01/31/2023) before conducting this activity.

Thanks,  
Alisha

**Alisha A. Etheredge, MS, MPH**  
ADS, Human Subjects and PRA  
2019 Novel Coronavirus Response  
404-797-6726  
[aetheredge@cdc.gov](mailto:aetheredge@cdc.gov)

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**From:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Sent:** Monday, March 23, 2020 4:40 PM  
**To:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Subject:** RE: Covid seroepi investigation protocol

Hi Alisha,  
Thanks so much for your review and feedback. I have accepted all changes and attempted to address the comments in the attached version. I included one marked up with responses to comments and another clean version.

Thank you,

Holly

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**From:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Sent:** Monday, March 23, 2020 1:51 PM  
**To:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Subject:** RE: Covid seroepi investigation protocol

Holly, thanks for the call today. Attached are comments on the submitted protocol.

Thanks,  
Alisha

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**From:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Sent:** Monday, March 23, 2020 9:53 AM  
**To:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>; Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Subject:** RE: Covid seroepi investigation protocol

Hi Alisha,  
Yes, would be happy to. I am free any time after 1pm.

Thanks,  
Holly

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**From:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Sent:** Monday, March 23, 2020 7:48 AM  
**To:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>; Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Subject:** RE: Covid seroepi investigation protocol

Hi Holly and Jackie,

Thank you for submitting a research determination request for the project titled, "Investigation of SARS-CoV-2 Seroprevalence and Factors Associated with Seropositivity in a Community Setting". Would you happen to have some time today to discuss this project?

Thanks,  
Alisha

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**From:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Sent:** Friday, March 20, 2020 9:40 PM  
**To:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>; Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Subject:** RE: Covid seroepi investigation protocol

How about this one?

Jackie

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**From:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Sent:** Friday, March 20, 2020 9:37 PM

**To:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Subject:** RE: Covid seroepi investigation protocol

That one's not working either. I tried saving it and then opening but still get the same message about "unreadable content" and a file error.

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**From:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Sent:** Friday, March 20, 2020 9:29 PM  
**To:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Subject:** Re: Covid seroepi investigation protocol

Hi Alisha,  
I hope this one will open.

Thanks,  
Holly

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**From:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Sent:** Friday, March 20, 2020 9:12 PM  
**To:** Biggs, Holly (CDC/DDID/NCIRD/DVD)  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD)  
**Subject:** RE: Covid seroepi investigation protocol

Hi Holly,

Sure, happy to help! I'm not able to open the file you attached, though. Would you mind resending?

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**From:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Sent:** Friday, March 20, 2020 9:05 PM  
**To:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Subject:** Re: Covid seroepi investigation protocol

Hi Alisha,  
We have developed a COVID-19 seroepi protocol that we would like to submit for HSR and PRA determination (attached). Can you help with the current process to submit this?

Thank you,  
Holly

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**From:** Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Sent:** Friday, March 20, 2020 6:58 PM  
**To:** Vagi, Sara J. (CDC/DDPHSIS/CPR/DEO); Biggs, Holly (CDC/DDID/NCIRD/DVD)  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD)  
**Subject:** RE: Covid seroepi investigation protocol

Hi Sara,

Yes! I'm still handling HSR and PRA determinations for the response. Holly, feel free to reach out!

Thanks,  
Alisha

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**From:** Vagi, Sara J. (CDC/DDPHSIS/CPR/DEO) <[hgg2@cdc.gov](mailto:hgg2@cdc.gov)>  
**Sent:** Friday, March 20, 2020 5:37 PM  
**To:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>; Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <[epq5@cdc.gov](mailto:epq5@cdc.gov)>  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Subject:** RE: Covid seroepi investigation protocol

Last I heard, these should go to Alisha Etheredge. I've been in the field and lost touch with what's happening back at the ranch.

Alisha are you still handling determinations?

*Sara*

Office Phone: 404-639-0879 | Mobile Phone: 404-772-9348

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**From:** Biggs, Holly (CDC/DDID/NCIRD/DVD) <[xdc6@cdc.gov](mailto:xdc6@cdc.gov)>  
**Sent:** Friday, March 20, 2020 2:35 PM  
**To:** Vagi, Sara J. (CDC/DDPHSIS/CPR/DEO) <[hgg2@cdc.gov](mailto:hgg2@cdc.gov)>  
**Cc:** Tate, Jacqueline E. (CDC/DDID/NCIRD/DVD) <[jqt8@cdc.gov](mailto:jqt8@cdc.gov)>  
**Subject:** Covid seroepi investigation protocol

Hi Sara,

We (Epi Studies and Surveillance Platforms Team/Epi TF) have developed a protocol for a community seroepidemiological investigation that we would like to submit for HSR and PRA determination. Are you still the right person to reach out to for human subjects review?

Thank you,  
Holly

Holly Biggs, MD, MPH  
Medical Epidemiologist  
Respiratory Viruses Branch  
Division of Viral Diseases  
National Center for Immunization and Respiratory Diseases  
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