

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

From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP)
Sent: Thursday, April 2, 2020 4:30 PM
To: Rolfes, Melissa (CDC/DDID/NCIRD/ID)
Cc: Mosites, Emily (CDC/DDID/OD); Ko, Jean Y. (CDC/DDNID/NCCDPHP/DRH)
Subject: FW: Homeless shelter COVID screening: HSR and PRA determination
Attachments: covid19_appendix a homeless shelter modified screener_4-1-20.docx; Covid19_homelessness atlanta proposal_4-2-20_clean.docx; Covid19_homelessness atlanta proposal_4-2-20_tracked.docx; covid19_appendix b symptom follow-up_4-2-20.docx

Melissa,

Thank you for submitting a research and PRA determination request for the project titled, "Assessing SARS-CoV2 Infection among Persons Experiencing Homelessness".

The purpose of this project is to investigate the point prevalence of SARS-COV-2 in people experiencing homelessness who are seeking shelter and to assess the ability of a symptom-based screening tool to effectively cohort individuals within a shelter. Because this project is necessary to allow CDC to assess conditions of public health importance, it meets the definition of public health surveillance under 45 CFR 46.102(I)(2).

PRA applies to this activity, as data will be collected from more than ten persons using the attached data collection instrument. This activity utilizes a slightly modified version of the household/close contact investigation form, which is approved for use under the Emergency Epidemic Investigations GenIC (OMB Control No. 0920-1011, expiration date: 4/24/2020). Please reach out to me if you anticipate that the data collection will extend beyond the expiration of the GenIC (April 24th).

Thanks,
Alisha

From: Rolfes, Melissa (CDC/DDID/NCIRD/ID) <ydi8@cdc.gov>
Sent: Thursday, April 2, 2020 11:04 AM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Cc: Mosites, Emily (CDC/DDID/OD) <lwx7@cdc.gov>; Ko, Jean Y. (CDC/DDNID/NCCDPHP/DRH) <fob1@cdc.gov>
Subject: RE: Homeless shelter COVID screening: HSR and PRA determination

Hi Alisha, thank you very much for this feedback.

Our intent is that this description be used as the protocol for this project. With that in mind, we've incorporated more information about the data will be collected, stored, and analyzed for this project in the homeless population.

A tracked and clean protocol is attached.

We've also added a question about smoking so have attached an updated data collection tool. Again, thank you for your continued review and feedback. Please let us know if there are further questions.
Melissa

Melissa AR Rolfes, PhD MPH

From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Sent: Wednesday, April 1, 2020 9:04 PM
To: Rolfes, Melissa (CDC/DDID/NCIRD/ID) <ydi8@cdc.gov>
Cc: Mosites, Emily (CDC/DDID/OD) <lw7@cdc.gov>; Ko, Jean Y. (CDC/DDNID/NCCDPHP/DRH) <fob1@cdc.gov>
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Thanks Melissa! This looks great. My only other question is regarding the actual protocol. Will you use the case-contact protocol that's been floating around or does this project description take the place of a protocol? You stated that "A far-more concise version of the GenIC form is being used." However, that's in reference to the data collection forms (I'm assuming) and not the protocol. If the protocol will not be used, would you mind adding a section within the project description regarding how the data will be stored and shared (i.e., what safeguards will be put in place to protect the data, how will it be stored, will data be shared and if so, with whom?)?

From: Rolfes, Melissa (CDC/DDID/NCIRD/ID) <ydi8@cdc.gov>
Sent: Wednesday, April 1, 2020 8:44 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Cc: Mosites, Emily (CDC/DDID/OD) <lw7@cdc.gov>; Ko, Jean Y. (CDC/DDNID/NCCDPHP/DRH) <fob1@cdc.gov>
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My apologies, see attached

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From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
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Subject: RE: Homeless shelter COVID screening: HSR and PRA determination

Thanks Melissa! Can you attach the tracked changes version of the proposal? I think you might have forgotten to attach it. It will help me review much quicker so I can get the determination out to you 😊

From: Rolfes, Melissa (CDC/DDID/NCIRD/ID) <ydi8@cdc.gov>
Sent: Wednesday, April 1, 2020 8:20 PM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Cc: Mosites, Emily (CDC/DDID/OD) <lw7@cdc.gov>; Ko, Jean Y. (CDC/DDNID/NCCDPHP/DRH) <fob1@cdc.gov>
Subject: RE: Homeless shelter COVID screening: HSR and PRA determination

Hi Alisha, We really appreciate your fast review. We've addressed your comments in the attached (clean and tracked versions are attached) and included the screener questionnaire that has been adapted from the GenIC OMB form.

Please do let us know if there are others things that need to be address.
Thank you,
Melissa

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From: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
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Cc: Mosites, Emily (CDC/DDID/OD) <lw7@cdc.gov>; Ko, Jean Y. (CDC/DDNID/NCCDPHP/DRH) <fob1@cdc.gov>
Subject: RE: Homeless shelter COVID screening: HSR and PRA determination

Hi Melissa,

Thanks for submitting. Please see my comments within the submitted proposal.

Thanks,
Alisha

From: Rolfes, Melissa (CDC/DDID/NCIRD/ID) <ydi8@cdc.gov>
Sent: Wednesday, April 1, 2020 9:03 AM
To: Etheredge, Alisha (CDC/DDNID/NCEH/DEHSP) <epq5@cdc.gov>
Cc: Mosites, Emily (CDC/DDID/OD) <lw7@cdc.gov>; Ko, Jean Y. (CDC/DDNID/NCCDPHP/DRH) <fob1@cdc.gov>
Subject: Homeless shelter COVID screening: HSR and PRA determination

Hi Alisha,

I'm writing to request a human subjects review and PRA determination for the attached proposal.

I am requesting that this be review for a non-research determination as this activity is part of the public health response in these shelter settings. Additionally, shelter activities are likely starting as early as April 6, so an expeditious review would be wonderful.

In summary, several homeless shelters in the Atlanta metro area are engaging in systematic testing of the shelter population and we are proposing to capture some additional demographic and medical history information on those screened. We are also proposing to conduct follow-up symptom assessments and retrospective medical chart review on those found to be SARS-CoV-2 positive.

These activities may already fall under the larger epidemiologic investigation of novel coronavirus that CDC is conducting across the US, but because of the vulnerable population we wanted to run the protocol and forms by you before proceeding.

Thanks and please do let me know if there are questions.
Melissa

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