

Attachment 4b - Consent Form

COVID-19 Community Seroepidemiological Investigation

Parent/Guardian Consent for Minor 0-<18 years old

Assent additionally required for Children 7-17 years old

Individual ID# _____

The Centers for Disease Control and Prevention (CDC) is working together with Georgia Department of Public Health and Fulton and Dekalb Counties to learn more about the spread of COVID-19 (also called SARS-CoV-2) in communities.

To do this, we are talking to randomly selection households about COVID-19. We want to get a better idea of how many people in the community have been infected with SARS-CoV-2 (the virus that causes COVID-19), which will help the CDC and other public health officials make decisions about next steps in the response to COVID-19. Your house is one that has been randomly selected in your community.

We would like your child/ward to participate. Participation is entirely voluntary. If you agree to allow them to participate, we will conduct an interview with them or ask you to provide responses for their behalf for a child <7 years old using a standardized questionnaire. The questionnaire will collect information about your child/ward, including about their health. They/you can choose not to answer any questions that they/you might be uncomfortable with. We would also like to collect a blood sample from your child/ward to test for antibodies that would indicate past infection with SARS-CoV-2. This will not tell us if your child/ward is currently infected with SARS-CoV-2. The amount of blood collected will not exceed what is recommended for your child's weight and age. Risks of blood collection include discomfort with the needle stick, a small risk of bruising, redness or swelling around the site, a small risk of feeling lightheaded or fainting when the blood is drawn, and a rare risk of infection. There is no direct benefit to you or your child/ward from the blood draw, but your participation will help us learn more about COVID-19 and its spread in communities.

If you agree that your child/ward can participate, we will send your child's/ward's blood sample to the Centers for Disease Control and Prevention in Atlanta, GA for testing for antibodies to SARS-CoV-2. We will store what is left of the blood sample for other studies that we may do in the future related to the virus SARS-CoV-2. All your records, samples, test results, and interview answers collected for this investigation will be kept private.

The testing method for antibodies to SARS-CoV-2 is still being developed and is not yet an approved diagnostic test (CLIA approved test) as of 4/16/2020. CDC is working to obtain CLIA approval. CDC might get approval and if CLIA approval is obtained, individual serology results could be reported back to participants. The timeline for potentially being able to report results back is likely several months.

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The results of these tests will help us understand how many people in a community have already been infected with SARS-CoV-2, which is important information to help public health officials make decisions about next steps in the response to COVID-19.

The participation of your child/ward in this investigation is voluntary, and you may withdraw your consent and decide at any time. The interview and blood draw are expected to take about 30 minutes per person. If you have any further questions, you may call (state/local jurisdiction/CDC) at xxx-xxx-xxxx.

For children aged 7 years or older, we will also be asking them for their assent to participate.

1. Have all of your questions about this public health investigation been answered?
 Yes No
2. Do you agree that your child/ward can be interviewed?
 Yes No
3. Do you agree that we can collect a blood sample from your child/ward?
 Yes No
4. Would you like to obtain your child's individual serology results if CDC is able to obtain CLIA approval for the assay?
 Yes No
5. May we contact you if we have any further questions?
 Yes No

If YES, Phone no: _____ Email: _____

6. Would you be willing for us to contact you in the future to request a follow up blood sample (if needed) from your child/ward?
 Yes No Maybe

If YES or MAYBE, we will contact you in the future if we want to obtain blood samples.

Signature of parent/guardian Date

Name of parent/guardian Date

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Assent of Minor \geq 7 years old

I understand that this investigation is about SARS-CoV-2 (also called COVID-19). I understand that the interviewer will ask me questions about myself, including about my health, and that a blood sample will be taken. My questions have been answered, and I know that I can ask questions later if I have them.

I agree to be interviewed Yes No

I agree to have a blood sample taken Yes No

Signature of child/minor _____

Date _____

Print name of child/minor _____

Name of person obtaining consent/assent _____ Date _____

Signature of person obtaining consent/assent _____ Date _____