

HEROS Study
Human Epidemiology and Responses to SARS-CoV-2 Study
Information Sheet

COVID-19, or coronavirus disease of 2019, is an ongoing public health problem. The HEROS study is needed to learn more about how many people may have the coronavirus without knowing they are sick, particularly children. The HEROS study will also help us learn how the virus spreads from person to person and how the nose reacts if the coronavirus is there. Your child and one caregiver are needed to volunteer. Another caregiver and another child living in your family home may also volunteer if they want.

Please note that at this time we are not able to give you any results from the tests that will be run. The samples that are collected will not be tested immediately; they will be stored and later run altogether. The laboratory that runs these tests is a research laboratory, and most research laboratories are not certified to report results for clinical purposes.

- Your participation is voluntary.
- You may ask questions at any time by contacting your study team.
- You may change your mind at any time.

This study will last about 24 weeks.

What you will need to do from your home (Everything will be done from your home; you will not go to a medical center for these visits):

- Read this information sheet and decide if you and your family will participate.
- Answer some questions about your child, yourself and all the other members of the household who have agreed to be part of the study.

For each person who volunteers:

- A kit will be mailed to your home to collect the following from your child, yourself and the other members of the household who have agreed to be part of the study:
 - A nose sample every 2 weeks for 18 weeks (9 samples)
 - A stool (poop) sample at the beginning of the study
 - A blood sample using a collection device. This device attaches to your skin and is safe to use at home. It is not the usual way you have blood drawn.
 - The blood is collected on people that are 2 years or older:
 - one time during the first 4 weeks after you begin to volunteer
 - at the end of 18 weeks
- Answer some questions on your phone, computer or over the phone each time you collect samples
- Mail the samples you collect in pre-addressed pre-paid mailer

You'll get a message every week to check if you or a member of your household are sick. If someone in your home is sick, you will complete a questionnaire about the symptoms. Your answers will determine if you need to collect the following from all members of the household who agree:

- A stool (poop) sample (right away)
- A nose sample (right away)
- A blood sample using a collection device (3 weeks after symptoms started)

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The last part of the study (week 24):

This may occur in your home or a visit to a medical center

For each person who volunteers:

- You will answer some questions
- The following samples may be collected:
 - Two samples from the nose
 - A saliva (spit) sample
 - A blood sample

If you agree to participate in this study, you will watch videos and look at pictures to learn how to collect the samples. Instructions on how to collect the samples will also be in the sample kits sent to your home. The study staff will be available to guide you so that you can do this at home.

Risks

Collecting samples may increase your risk of getting sick. A mask and gloves are provided for added protection.

The liquid into which you will put the swabs is in a tube with a cap and comes with absorbent wrap in the package in which they are mailed in case they leak during shipping. If the liquid gets on your skin, there is a possibility that you may experience skin irritation and you will need to wash it off your skin. Gloves are provided for added protection.

Although we will take steps to protect the confidentiality of those participating in this study, there is a small chance that there could be a loss of confidentiality, meaning someone sees your family's information when they do not have permission. To lower this risk, we will use special codes to label samples, questionnaires, forms, and other information instead of names. However, we cannot completely remove this risk. Also, it is possible that in the future someone could figure out how to use the health or genetic information to identify individuals or their close biological relatives. The risk of this happening is very small.

You will be notified if any new risks are identified during this study.

Discomforts

- **Nose Sample** – Will feel a little uncomfortable and, sometimes, it may cause slight nose bleeding.
- **Blood Draw** – The device causes mild discomfort and there is a small risk of infection. This device attaches to your skin and is safe to use at home.
- **Stool Sample (poop)** – No discomforts

Payment

Your family will receive compensation based on how many samples you collect and study surveys you complete. Your family will be compensated approximately \$420 or more in gift cards over the 6-month period of the study.

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You will receive newsletters that will keep you up to date about the study progress and provide information about the coronavirus that causes COVID-19.

Personal Information

We will collect names, address, phone number, and date of birth from you and the family members who are in the study. This information will be collected and stored at Vanderbilt University and safeguards to protect your information will be taken. This information will be shared with the company that works for this study and is sending the kits to your home. Also, the researchers and staff will see this information. Any other records or results from you or from the members of your household that will take part in this study will be confidential to the extent permitted by law. If there is a legal obligation to report results, we will inform you.

Storing Samples for Future Use

The nose samples and blood samples that you collect will be used for genetic research to learn more about COVID-19. Your samples include your DNA. The DNA will only be used to study the COVID-19 virus. The genetic tests will study genes that are made up of DNA. Genes are present in each of the cells of your body and contain information needed for the human body to grow and function. Genes are passed down or “inherited” from parents to their children.

NOTE: Your name will not be associated with the samples you provide. No one who works with the DNA will know that it is your DNA.

This study does not provide any health care. All your health care is done with your doctor. If at any time you become sick, contact your doctor or go to the emergency room.

This study is funded by the National Institute of Allergy and Infectious Diseases (NIAID), Division of Allergy, Immunology and Transplantation (DAIT), National Institute of Health.

Each member of your household who wishes to take part in this study has reviewed this information sheet and agrees to take part in the surveys and sample collections.

Please Check below.

Yes _____