

Cover Page

Official Title: Test to Stay in School: COVID-19 Testing Following Exposure in School Communities (Pro00109436)

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**Consent to Participate in a Research Study
ADULT/PARENT**

Test to Stay in School: COVID-19 Testing Following Exposure in School Communities

Study Title: Test to Stay in School: COVID-19 Testing Following Exposure in School Communities

Principal Investigator: Kanecia Zimmerman, MD

Contact information for questions: SchoolSETStudy@duke.edu

Study Summary

- You or your child have been exposed to SARS-CoV-2 (the virus that causes COVID-19).
- If you choose to participate in this study, you or your child, will be allowed to remain on school premises as long as you continue to test negative for COVID-19.
- You or your child will be tested for COVID-19 at up to four times per the study protocol.
- You or your child will be asked by the school nurse or other school personnel to provide information about yourself, masking practices, and details about the SARS-CoV-2 exposure.
- Study researchers will have your name and contact information as part of this consent form, but all additional information you provide to the school nurse, and testing information (test day after exposure, result, symptoms) will be provided to the study researchers by your school without any information that can directly connect the information to you or your child.

Who is doing this research?

This study is led by researchers at Duke Clinical Research Institute (DCRI) and funded by the National Institute of Child Health & Human Development (NICHD).

Why is this study being done?

We're doing this study to learn more about SARS-CoV-2 spread in schools following SARS-CoV-2 exposure. We hope that this study data will help us understand if it is safe to remain in school following exposure as long as COVID-19 testing remains negative. Any student or staff member at participating schools can participate in this study.

How long will I be in this study?

Once you consent for yourself or your child, you or your child will be enrolled in this study for the entire school semester. As such, you or your child will be asked to follow study procedures after each SARS-CoV-2 exposure during the semester. You do not have to participate in this study. Your alternative option is to follow your (or your child's) local school guidelines for quarantine following SARS-CoV-2 exposure. You may withdraw yourself or your child from the study at any time and no further data will be collected, however, all data provided up to that point will be maintained by researchers. Withdrawal requests should be sent in writing to SchoolSETStudy@duke.edu.

What are the benefits/risks?



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- You or your child may benefit from knowing COVID-19 testing results following exposure and the ability to remain in in-person school following exposure (as long as your COVID-19 tests remain negative following exposure).
- Risks of COVID-19 testing include mild irritation, local pain, and minor bleeding.
- There is a potential risk of loss of confidentiality. Every effort will be made to protect you or your child's personal information.

Will my information be kept private?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you or your child is kept confidential, but we cannot guarantee total confidentiality. Your or your child's personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. Reviewers may include representatives and affiliates of NICHD, the Duke University Health System Institutional Review Board, and others as appropriate.

This project has a Certificate of Confidentiality from the United States government to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

- 1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
- 2) you have consented to the disclosure; or
- 3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about your or your child's involvement in this research. If you want research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your or your child's privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

All information collected by this study will be stored on a secure third party system with many layers of protection. We will protect your or your child's data by:

- Keeping it in a secure, encrypted database with restricted, monitored access



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- Complying with applicable state and federal laws that protect the privacy and security of your health information

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This Web site will not include information that can identify you or your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who will have access to my data and in what form?

By agreeing to take part, the information you share may be used by other researchers in the future. Your or your child's name will not be used. These researchers may include academic, biopharma, medical device, patient advocacy, and other healthcare and life sciences entities. If your or your child's data are used in this way, identification information (name, email address) will be removed. By consenting to take part, you agree to allow access to your or your child's data for these reasons.

What are the costs and will I get paid?

COVID-19 testing will be provided to you or your child free of charge, as part of participation in this study. There is no commitment by Duke University, Duke University Health System, Inc., DCRI, or the principal investigator to provide monetary compensation or free medical care to you or your child in the event of a study-related injury. No compensation will be provided for participation in this study.

Who do I call if I have questions or problems?

- For questions about the study, or if you have problems, concerns, questions or suggestions about the research, contact SchoolSETStudy@duke.edu.
- For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

NOW IT'S TIME TO GIVE YOUR CONSENT TO THE STAY IN SCHOOL STUDY!

By agreeing to take part in this study or to have your child take part in this study, you are agreeing that:

- You or your child will participate in the study that is described in this consent form.
- Duke researchers who are working directly with your or your child's school will collect the following identifiable information: name and contact information.

The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been told whom to contact if I have any questions. I have read this consent form and agree that myself or my child will participate in this study with the understanding that I may withdraw myself or my child at any time. I have been told that I will be given a signed copy of this consent form.

You can review this information as many times as you'd like. You can reach out to us with questions at SchoolSETStudy@duke.edu.



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First and Last Name (Adult/Parent): _____

Child's Name (if applicable): _____

Email Address: _____

School Name (the study team will notify the school district representative of your or your child's participation): _____

Signature (Adult/Parent): _____