ReSET Aim 1b: Restarting Safe Education and Testing for Children With Medical Complexity - COVID-19 Testing in School With Children and Staff

11/21/2022

NCT04899245

UNIVERSITY OF WISCONSIN-MADISON

Subject CONSENT to Participate in Research
And
AUTHORIZATION to Use and/or Disclose Identifiable Health information for Research
For Parents/Guardians

Study Title for Participants:	**Year 2 -** ReSET Study - Restarting Safe Education and Testing for Children with Medical Complexity
Formal Study Title:	**Year 2 -** ReSET Aim 1b: Restarting Safe Education and Testing for Children with Medical Complexity - SARS-CoV-2 testing in school with children and staff
Lead Researchers:	Ryan Coller, MD, MPH / 608-263-9408 Pediatric Complex Care, American Family Children's Hospital Department of Pediatrics, Division of Hospital Medicine University of Wisconsin School of Medicine and Public Health Gregory DeMuri, MD, FAAP / 608-265-6050 Department of Pediatrics, Division of Pediatric Infectious Diseases University of Wisconsin School of Medicine and Public Health

INVITATION

You and your child are invited to participate in this research study about COVID-19 testing and returning to school. You and your child are invited because your child is attending Waisman Early Childhood Program (WECP). If you have more than one child enrolled at WECP and eligible for the study, they are also invited to participate. This is the same study you may have participated in during the 2021-2022 school year.

Please confirm:

____ (initials) Yes, my child is attending the summer session at Waisman and/or will be attending in the fall.

You and your child's participation in this research study is voluntary. If you decide not to participate, the health care provided to your child by the University of Wisconsin-Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics and the University of Wisconsin Medical Foundation) will not be affected in any way.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the research is to learn about the factors that parents and staff consider when deciding whether to attend school in-person and to see whether parents find in-home testing for COVID-19 valuable. We are using a testing system called the BinaxNOW nasal swab test. The use of the BinaxNOW system is authorized under the Food and Drug Administration's Emergency Use Authorization. The test is allowed for over-the-counter, non-prescription use with or without symptoms. The test may be used with children two years and older with the help of sample collection by an adult, and the test may be self-administered by anyone aged 15 years or more.
The study will include about 50 students and their parents enrolled at WECP. Funding for this study is provided by the National Institutes of Health. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT WILL MY CHILD'S PARTICIPATION INVOLVE?

If you decide to let your child participate in this study, we will provide you with in-home BinaxNOW testing kits and recommend you test your child:

1) when your child has symptoms compatible with COVID-19*

OR

2) has had a known exposure to someone with COVID-19.

* fever, chills, runny nose, cough, loss of taste or smell, sore throat, difficulty breathing, nausea, vomiting, diarrhea, body aches, or headache

The BinaxNOW test is a nasal swab test in which a swab is inserted into your child's nostril about a ½ inch and gently swirled a few times, then repeated in the other nostril. The results are available in 15 minutes and most people report no discomfort from the test. It is simple to perform and, if you are new to the study, study staff will give you instructions on how to conduct the test.

WHAT DOES MY PARTICIPATION INVOLVE?

Parents in this study will asked to complete a 15-minute survey at the start of the study, at month 3, month 6, month 9 and at the end of the study. This quarterly survey takes about 15 minutes to complete and asks about your perceptions about testing and returning to school. The survey is done online. You may complete the survey by yourself or ask study staff to assist you. Parents will be trained on how to perform the BinaxNOW Self-Test at home when their child has symptoms of COVID19 and how to report these results to study staff.

DO I NEED TO LET STUDY STAFF KNOW IF I DO A TEST?

If the test is negative:

If your child is symptomatic and the initial test is negative, test again using a Binax NOW test in 48 hours over 3 days. Report the test results in your weekly log.

If your child is not symptomatic and the initial test is negative, test 2 more times using Binax NOW test kits at least 48 hours apart over 5 days. Report the test results in your weekly log.

It is important to note that the COVID swab test tells you whether someone has COVID right now, at the time the test is done. It cannot tell you whether they have had COVID-19 in the past or whether they

may be positive tomorrow. After someone is exposed to another person with COVID-19 it takes several days for them to show that they are infected by having a positive test. In the first few days after exposure, their test will be negative. Just before they develop symptoms their test usually becomes positive and stays positive for several more days.

If the test is positive:
If your child is symptomatic and the initial test is positive, no need to repeat Binax Now test. Arrange to obtain a PCR test within 48 hours to confirm whether the in-home test was accurate. Report the test results on your weekly log.

If your child is not symptomatic and the initial test is positive, no need to repeat Binax NOW testing. Arrange to obtain a PCR test within 48 hours to confirm whether the in-home test was accurate. Report the test results on your weekly log.

The PCR test detects genetic material that is specific to the virus within days of infection, even in those who have no symptoms. The test is done in a clinic, hospital, or community center. Study staff can assist you in arranging to obtain a PCR test. The PCR test results are generally available between 24 hours and 3 days after the test.

If your child's in-home test is positive, you are advised to restrict your child from school activities per public health guidelines until the results of the PCR test are known. If the PCR test comes back with a negative result and your child is attending school in-person, your child may return to school the next day (or if symptomatic, once symptoms resolve). If the PCR test comes back with a positive result, you are advised to keep your child at home per public health guidelines.

No matter what the results of the tests are, you should not assume that your child can relax the prevention measures they have been doing, such as frequent hand washing, wearing a face mask in indoor spaces that are not their home, covering their coughs, and sneezes, physical distancing, and staying home when possible. You (or your insurance company) will be responsible for costs related to any follow-up care.

If my child has a positive PCR, when should I resume testing?
Recommendations on when you can test for COVID-19 after a positive PCR have changed since last summer. In year 2, you can resume BinaxNOW in-home testing *21 days* after a positive result. It is recommended that you wait to do a PCR test for *90 days* following a positive PCR. If your child requires a PCR before 90 days (for example, if they require one for a hospitalization or procedure), follow the guidance of your healthcare provider.

HOW LONG WILL MY CHILD AND I BE IN THIS STUDY?
This study is approximately 52 weeks long, depending on when you start the study and when your child's school year ends. Most parents will participate from June 2022 through early June 2023.

WILL BEING IN THIS STUDY COST ME ANYTHING?
There is no cost to participating in this study.

WILL I BE PAID FOR MY CHILD'S PARTICIPATION?

You will receive $200 for completing the study. A stipend of $50 will be paid at month 3 (August), month 6 (November), month 9 (February), and at the end of study (June). Your child will not receive a stipend. BinaxNOW Self-Test kits for in-home testing will be provided at no cost.

ARE THERE ANY BENEFITS TO ME OR MY CHILD?

The results of the study may help researchers advance their understanding of in-school testing on parent perceptions about testing and attending school in-person.

ARE THERE ANY RISKS TO ME OR MY CHILD?

- The BinaxNOW nasal swab may be slightly uncomfortable for your child. The swab is inserted into the nose about ½ inch and twirled around 3 times. Then the other nostril is sampled. If the first test is positive a second nasal swab test will be performed. The second test (called a PCR nasopharyngeal test) is also a nasal swab test but the tip of the swab is inserted further into the nasal cavity; it is uncomfortable but only lasts a few seconds. Should you or your child decline the testing portion of this study, you may remain in the study to complete the study surveys.
- It is possible for the test to give a negative result that is incorrect (false negative) in someone with COVID-19. This means that even though your child's test is negative, they could still have the infection that causes COVID-19. If someone believes that they had a negative test result for COVID-19, they might stop following measures they would otherwise take to protect themselves from COVID-19 like frequent handwashing, mask-wearing, or social distancing. If this happens, and the test was wrong, relaxing these measures could make it MORE likely for your child to be exposed to COVID-19, or to expose someone else. This is why it is important to follow public health recommendations no matter what the results of the test show.
- Some parents may find the completion of study surveys distressing or burdensome. You may choose not to answer any survey question or skip the surveys entirely. If you choose to skip certain questions or the surveys, your child may continue to participate in the testing portion of the study.
- Another risk of taking part in this study is that your child's study information could become known to someone who is not involved in performing or monitoring this study. A breach of confidentiality could result in damage to your or your child's reputation, but the chances that this will happen are very small. We will take every precaution to keep your child's health information private.

ARE THERE OTHER CHOICES IF MY CHILD DOES NOT TAKE PART IN THIS STUDY?

Your child does not have to be in this research study to get a test for COVID-19. If you decide not to have them take part in the study, they have other choices. They could get a test for COVID-19 through your health care provider, or at a free community testing site. The BinaxNOW testing cards are available for purchase at area pharmacies for over-the-counter, home use.

This study is not a substitute for your child's regular medical care. They should continue to see or consult with your regular medical providers.

PROTECTED HEALTH INFORMATION (PHI) USED IN THIS STUDY

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Your responses to our interviews and surveys
- Test results

The results of your child's in-home testing will not be reported to school or health authorities by the study team. The results of PCRs (positive and negative) performed at a doctor's office or community testing site are reported to the Wisconsin Department of Health Services in compliance with state statutes §252.05 using the Wisconsin Electronic Disease Surveillance System (WEDSS). WEDSS is a secure, web-based system designed to facilitate reporting, investigation, and surveillance of communicable diseases in Wisconsin. It is designed for public health staff, infection control practitioners, clinical laboratories, clinics, and other disease reporters.

HOW WILL RESEARCHERS KEEP MY CHILD'S AND MY RESEARCH INFORMATION CONFIDENTIAL?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative. The study team has a Certificate of Confidentiality from the National Institutes of Health for this study. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent.

Others at UW-Madison and its affiliates who may need to use your child's health information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison
- Research support services staff at the UW-Madison and its affiliates

Others outside of UW-Madison and its affiliates who may receive your child's health information in the course of this research:

- The U.S. Food and Drug Administration (FDA)
- The study sponsor, the National Institutes of Health (NIH)
- An optional request to share additional information with the NIH and the research group they have hired to oversee the data collection appears towards the end of this consent form.

DOES MY CHILD HAVE TO BE IN THIS STUDY? WHAT HAPPENDS IF I SAY "YES" NOW AND CHANGE MY MIND LATER?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. You can also decide at any time to participate in just some of the study activities. For example, you may choose to do the COVID-19 testing but not complete the study surveys, or vice versa. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study. Let the researchers know if you choose to leave the study.

IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, your child cannot take part in this research study. You may completely withdraw your child from the study at any time.

If you decide not to let your child participate in this study, or decide to have them stop later on, the education your child receives at school will not be affected in any way. If you or anyone in your family have a relationship with the UW-Madison and its affiliates, or receive health care there, your decision not to participate will not affect them.

HOW LONG WILL MY PERMISSION TO USE MY CHILD'S HEALTH INFORMATION LAST?

By signing this form you are giving permission for your child's health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your child's health information, there is no end date for its use for this research study. You may withdraw your permission to be in the study at any time by writing to the person whose name is listed below:

Ryan Coller, M.D.
UW Dept of Pediatrics, 600 Highland Ave, Madison WI 53792-4108

Beginning on the date you withdraw your permission, no new information about your child will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, your child can no longer actively take part in this research study.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish your child to participate. If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Lead Researcher, Ryan Coller, MD at 608-263-9408. If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Lead Researcher, Ryan Coller, MD at 608-263-9408. If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.
If you have questions related to COVID symptoms, you may ask the study team or your child's primary care physician.

Authorization to communicate with you by email

We are requesting your email address so we can send you study reminder messages during the study. If you participated in a remote enrollment visit, staff will ask you to email photographs of your signed

consent form to them. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the Lead Researcher, Ryan Coller, MD at 608-263-9408. You do not have to provide your email address to participate in this study.

___ (initials) Yes, you may use email to contact me for this study.

___ (initials) No, I do not want to be contacted by email.

OPTIONAL STUDY ACTIVITIES - Consent to Share Your Re-SET Data with the National Institutes of Health

The following study activities are optional. You may still take part in this study if you say no to any or all of these optional activities. Participating in any of these activities will not help you or your child directly.

Consent to Share Your Re-SET Data with the National Institutes of Health

Dr. Coller and his research team received funding for the ReSET COVID testing study from the National Institutes of Health which funds a larger program called RADX-UP. The researchers overseeing RADX-UP are asking for your permission for us to share your Re-SET study data with NIH so they can learn more about COVID-19 and other diseases and conditions. The following consent form asks for your permission for us to share this study information. This is an optional, additional request. If you decline sharing your information with the NIH, your participation in the Re-SET study will not be affected.

What is the NIH and RADX-UP?

The NIH stands for the National Institutes of Health. The NIH is part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone. The NIH funded (provided support) for the RADx-UP program.

RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. If you join RADx-UP, we will gather some data (information) about you. We will combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

What will you ask of me?

If you decide to join this study, we will gather data (information) about you and your child. If you choose to participate in this data sharing, Dr. Coller and his team will share the information collected in the study surveys with the NIH/RADX-UP team. Examples of the information that we may collect from your study surveys are, but not limited to:

- basic information about you and your child such as name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information including address history
- information about COVID-19 related to you and your child, including information about any symptoms and test results. If you had a positive COVID-19 test, we will ask information about contact tracing (people who may have come in contact with you while you had COVID-19). We will ask about your child's medical history and if they have or have not had vaccines and why.

- information about you and your child's health, education, family, home, relationships, and social life, among others.

What will you do with my data?
We will keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP program. Researchers will use the data to learn more about COVID-19 or other diseases and conditions.

The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies.

The DCRI will build two RADx-UP databases (systems that hold electronic information).

The first database will only hold information that can identify you (called identifiable information). Examples are your name, address, email, and date of birth.

- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.
- Only if you agree, by initialing below, the DCRI will keep information that can identify you in order to contact you for future research studies. If you do not agree, this information will stay with your study team, as applicable.
- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI will be able to see this information.
- This database will contain the following identifiable information: name, date of birth, address, phone numbers, and email addresses of you and your child. This information will be paired with your responses to the study survey questions. Survey questions include information about your child's medical conditions, school attendance, health insurance type(s), vaccination status of you and your child, COVID testing history, your opinions about vaccinations and testing, household income, race, ethnicity, gender, your educational background, employment status, and marital status.

The second database will not hold information to identify you. It will hold all the nonidentifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for COVID19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this second database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.
- This database will contain the nonidentifiable information that you provide on the study surveys.

How will you protect my privacy?
Your privacy is *very* important to us. We will take great care to protect your privacy. However, there is always a chance that, even with our best efforts, your identity and/or information collected during this study may be accidentally released or seen by unauthorized persons. Here are a few steps we will take:

- Data will be stored on protected, secure computer systems. We will limit and keep track of who can see these data.
- Anyone who can see these data will have to use a password.
- We will take steps to protect your information from others that should not be able to see it.
- When your data are shared with other researchers, they will not have information that can identify you.
- This project has a Certificate of Confidentiality from the United States government. Certificates of Confidentiality protect your privacy by blocking the release of identifiable, sensitive research information to anyone not connected to the research except when you agree, or in a few other specific situations.

Optional:
I agree to let Duke Clinical Research Institute (DCRI) collect the following identifiable information: name, address, contact information, and date of birth, as stated above.

Yes, initials _____ No, initials _____

I agree to let the DCRI collect only my zip code and no other identifiable information as stated above.

Yes, initials _____ No, initials _____

I agree to be contacted for future research as stated above.

Yes, initials _____ No, initials _____

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you and your child cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____
Printed Name of Child Participant

_____
Printed Name of Parent Participant

_____ _____/_____/_____
Signature of Parent Participant Date

_____ _____/_____/_____
Signature of Person Obtaining Consent and Authorization Date

****You will receive a copy of this form****