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COV-IDD: Testing for Covid-19 in high risk Children with intellectual and developmental disabilities
e-Consent Form
V04.03.2023

UNIVERSITY of ROCHESTER MEDICAL CENTER

STRONG MEMORIAL HOSPITAL
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING

CONSENT FORM

COV-IDD: Testing for Covid-19 in high risk children with intellectual and developmental disabilities

Principal Investigator: John Foxe, Ph.D.

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- There are risks from participating and you should understand what these mean to you.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you work at Mary Cariola Center and interact with the students at Mary Cariola who are high risk of infection from COVID-19
- The purpose of this study is to understand how to prevent COVID-19 spread in a school like Mary Cariola by answering questions like these: how do activities in the school alter chances of infection? Are there people infected with the COVID-19 virus who have no symptoms? How is spread of COVID-19 affected by vaccination rates? Is there any hesitancy to get the vaccine and what are the reasons? This information will be used to help keep the school open and the students and staff safe.
- The study lasts for up to 36 months
- Your participation in this study will involve getting a COVID-19 test (nasal swab) approximately every 5-14 days for up to 36 months. If you test positive for COVID-19 we will ask you to get tested every 3 days for the next 10 days. We will also ask you to provide a blood sample when you enroll in order to see if you already have

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antibodies (natural resistance) to the virus that causes COVID-19. This test will be repeated every 6 months for up to 36 months

- We will ask you to provide a fingerstick blood test (just one or two drops of blood) to also test for antibodies. We will ask for this sample once a month for up to 36 months
- There are risks from participating.
    - The most common risk is discomfort during the COVID-19 test and discomfort during the blood sampling.
    - One of the most serious risks is breach of confidentiality.
    - Positive COVID-19 tests are required by New York State to be reported and documented
- There are some small benefits of this study for you. You will have access to free testing for COVID-19 and antibodies that are not generally available. There are no other direct benefits for you when you participate in this study.

Purpose of Study

Our goal is to establish COVID-19 testing for students and staff at the Mary Cariola Center to identify infections and prevent spread of the virus through the vulnerable populations at the center. The tests are Food and Drug Administration (FDA) approved and will be conducted by the URMC Dept. of Pathology and a URMC specialized testing team.

In addition if you decide to participate in this study, the results of the tests conducted and your information will be entered into a large research database called "Rapid Acceleration in Diagnostics (in) Underserved Populations (RADx-Up)." This database is funded by National Institutes of Health (NIH) and is a health research program to learn more about COVID-19 disease. The RADx-Up program involves the collection of information from multiple institutions which will be used for future research. While your information will be included in RADx-Up if you decide to participate in this study, you will be able to decide how your information will be identified when shared with RADx-Up. This is explained in the "Future Use of Information and Data Sharing" section (beginning on page 7), and the check boxes to decide how to share are in this section.

Description of Study Procedures

☐ *Procedure 1: Consenting to participate in the COVID-19 nasal swab test, and filling out a questionnaire.*

At the time of enrollment we will collect contact information and we will send an electronic survey via email to you that you can fill out on your phone, or on a computer. We will have tablet computers available on-site if you prefer to fill out the questionnaire

during your visit. We will ask you questions about household characteristics, your age, gender, race/ethnicity, and whether you have had a COVID-19 infection incident in your home. Other questions will include perceptions about COVID-19 and the risks of getting it, and whether you intend to receive COVID-19 vaccine when available. This should take around 20 minutes.

We will ask you to fill out this same set of questions a second time (around mid-May 2022 in order to see if things have changed since you first enrolled your child in the study.

We will schedule you to be tested for COVID-19 (RT-PCR) using fluid collected from your nose using a 'mid-turbinate swab'. This is the simpler and faster method for taking a nasal swab. You will be tested every 5-14 days for up to 36 months even if you have no symptoms. This will allow researchers to track spread even when people do not feel sick. This will take around 10 minutes.

☐ *Procedure 2: Consenting to participate in the fingerstick blood sample*

After getting the vaccination, or after having had COVID-19 your body's immune system creates its own defense system to protect you from getting it again. We will measure your body's protection (antibodies) by collecting a very small sample of blood (1-2 drops from your fingertip). To do this we will use a fingerstick to produce a drop of blood that we will collect. The total amount of blood will be one or two drops. We will do this at your first scheduled visit and then repeat it every month for up to 36 months in order to track how your body's defenses change over time. The procedure will take less than 5 minutes.

☐ *Procedure 3: Consenting to participate in the serologic (blood sample) testing.*

Different blood tests require different quantities of blood. We will also ask you to consent to providing a larger blood sample so we can use Food and Drug Administration (FDA) approved antibody testing. To use these tests we will ask you to provide a blood sample taken from your arm (4-8 ml of blood which is slightly more than a teaspoon). This blood sample will be taken using a small needle placed in a vein in your arm and collected in a small tube. This blood sample will be taken at your first scheduled visit, and then every 6-months thereafter for the duration of the study (up to 36 months). This procedure will take about 10 minutes.

Number of Subjects

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Approximately 800 total people may take part in this study: there are up to 450 students at Mary Cariola Center who are eligible, there are also 500 staff at Mary Cariola who are also eligible.

Duration of the Study
Testing procedures will take approximately 30 minutes – this will include filling out the questionnaire (only on the first visit) the nasal swab for testing you for COVID-19, the fingerstick and the blood sample from your arm.

Risks of Participation
There is risk of discomfort during the study when nasal swabs are taken to test for active COVID-19. You may experience some mild pressure or discomfort, a tickling sensation, occasional eye watering, or sneezing when the nasal swabs are collected. In rare instances swabbing inside the nose may cause very minor bleeding.

Small blood samples will be taken using a fingerstick – a small lancet to produce a few drops of blood. You will likely experience a small amount of pain at the site where the needle enters the skin. There is a very small risk of infection. Some people become lightheaded or feel faint at the sight of blood or when blood is drawn.

When having a blood sample taken from your vein (4-8 ml which is slightly more than a teaspoon), you may feel some discomfort from having the tourniquet placed around your arm. You will likely experience a small amount of pain at the site where the needle enters the skin. There is also a very small risk of bruising or infection at the site where the blood is taken. Some people become lightheaded or feel faint at the sight of blood or when blood is drawn.

Because this study involves collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. All data obtained will be kept confidential. You will be assigned a code under which your data will be stored. All data obtained from subjects enrolled in the study will be housed within the CNL laboratory or within REDCap. The password to the document that links identifying subject information to subject ID numbers will be managed by the study coordinator and given only to RSRB approved individuals. You will not be identified by name in any written or verbal report of the study.

Benefits of Participation
You might not benefit from being in this research study. The potential benefit to you from being in this study might be access to testing that could otherwise be more difficult to obtain. You will learn about your COVID-19 status and your antibody status.

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The information collected by this study may be put to use by Mary Cariola to determine if their COVID-19 mitigation procedures should be modified, this has indirect benefit by reducing potential exposure to individuals who could transmit the virus.

Unvaccinated Staff

Mary Cariola Center policy requires all employees who are not vaccinated to get weekly COVID-19 testing. Enrolling in this study and getting weekly tests as part of the study procedures is one way to satisfy this requirement. If you are enrolling in the study and are unvaccinated, , or if you have not told the study team about your vaccination status, **study team personnel are required to inform Mary Cariola center administrators if you miss a scheduled COVID-19 test.**

Sponsor Support
The University of Rochester is receiving funds from the National Institutes of Health to support parts of this study. All costs related to the fingerstick serology testing (finger stick blood sample) will be paid for by separate University of Rochester funds and not by the NIH.

Costs
There will be no cost to you to participate in this study.

Payments
When you enroll in the study and participate in the first set of tests you will receive a gift card worth $25. Once a month at your regular test visit when you have the nasal swab and/or the finger stick procedures you will get an additional gift card worth $10

You will receive an additional $25 for completing the second round of the questionnaire.

Reimbursement for Travel Expenses
Testing will take place at Mary Cariola Center so there will be no additional travel costs for you.

Circumstances for Dismissal
Under some circumstances, it may be necessary to discontinue your participation in the study. This will be done at the discretion of the investigators, and you will be paid for the amount of time you have participated in the study.

Early Termination
There are no consequences for subject self-withdrawal. Self-withdrawal may be initiated by contacting any member of the lab by phone or e-mail. In the event that this occurs,

your participation will be terminated. Data collected will be kept for analysis unless otherwise requested.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we store all data and personal information collected within password-protected storage locations. Furthermore, any reference to your name in our file-names, documents, and data is replaced with a unique, 8-digit study number. Sometimes, however, researchers need to share information that may identify you with people that work for the University, NY State Dept. of Health, other regulators, or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study
- Address and contact information

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- Mary Cariola Center
- The University of Rochester
- University of Rochester Accounts Payable

Why will this information be used and/or given to others?

- To do the research
- To study the results
- For public health and NY State regulatory requirements
- To see if the research was done correctly
- To provide payment

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Future Use of Information and Data Sharing

By participating in this study, you will become part of the RADx-UP program, which is funded by the NIH.

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. When you participate in this study you will join RADx-UP, which means we will gather some information about you and the results of test performed as part of this research and then

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combine this information with information 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. In this section you will be given the choice to determine if you want to share information that can identify you (called identifiable information). Examples are your name, address, email, dates related to study participation and gender.

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).

If you agree to provide information that identifies you…the first database will only hold this information. Examples are your name, address, email, and gender.

- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.
- 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
- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- 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.

The second database will hold all the other information collected as part of this study.

- 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.

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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.

Your information might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information is used or distributed.

(1) I agree to let the DCRI collect the following identifiable information: name, address, contact information, date of birth, and any/all dates related to study participation (consent, testing, results).

_____ Yes (enter initials), if you answer 'YES' skip question #2.

OR

_____ No (enter initials), if you answered 'NO' answer question #2.

(2) I agree to let the DCRI collect **only** my zip code and no other identifiable information

_____ Yes (enter initials)

OR

_____ No (enter initials)

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(3) I agree to be contacted for future research as stated above by either DCRI or the University of Rochester Neuroscience research team.

_____ Yes (enter initials)

OR

_____ No (enter initials)

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. John Foxe at 585-273-4586

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

If you are an employee, taking part in this research is not a part of your Mary Cariola duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

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Use of E-mail and Text Messaging

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Email communications between you and the study team may be filed in your research record.

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Appointment reminders and secure electronic links to the survey questionnaires can be sent to you via email or text message. Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email/text.

For text messages:
You are responsible for any fees charged by your carrier's service plan for text messaging.
You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says "Stop Research Text". Your consent, and any request to stop email or text messaging, applies to this research study only.

___ *I consent to the use of email in this study.*

___ *I consent to the use of text messaging in this study.*

SIGNATURE/DATES
After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

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Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date

RSRB Approval Date: 4/3/2023
Expiration Date: 4/2/2024

Consent Submission

Consent Form Selection(s) Summary

Question: Do you consent to participate in the COVID-19 nasal swab test, and filling out a questionnaire.
Answer: Yes

Question: Do you consent to participate in the fingerstick blood sample.
Answer: Yes

Question: Do you consent to participate in the serologic (blood sample) testing.
Answer: Yes

Question: I agree to let the DCRI collect the following identifiable information: name, address, contact information, date of birth, and any/all dates related to study participation (consent, testing, results).
Answer: No

Question: I agree to let the DCRI collect only my zip code and no other identifiable information.
Answer: Yes

Question: I agree to be contacted for future research as stated above.
Answer: No

Question: I consent to the use of email in this study.
Answer: Yes

Question: I consent to the use of text messaging in this study.
Answer: No

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Do you agree to participate in the study?

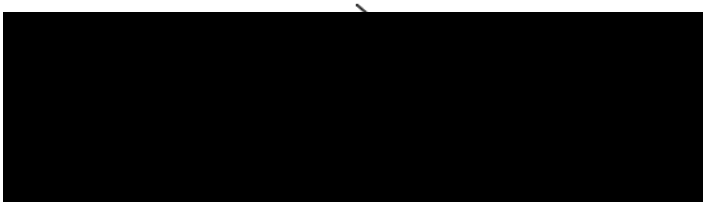
⊗ Yes

Subject's First Name [redacted]

Subject's Last Name [redacted]

Signature of Subject

Please click "Add Signature" to add your signature.



Person Obtaining Consent
I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

Samantha Spallina

Person Obtaining Consent Date Signed

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