Research Information Sheet
Prospective Assessment of COVID-19 in a Community
2022-2023 Respiratory Season Surveillance Period (PACC 3)

Marshfield Clinic Research Institute
800-468-9700 or pacc@marshfieldresearch.org

Please read the following information carefully before you make a decision. Ask questions if you do not understand any of the information.

What is the purpose of this research study?

- This study is needed to learn more about illness caused by new COVID-19 variants, the impact of COVID-19 vaccination and booster doses, and duration of protection after vaccination and infection in children.
- You were asked to join this study because you are under 18 years of age and participated in the Prospective Assessment of COVID-19 in a Community (PACC) study. We want as many of the study participants as possible to participate for the 2022-2023 surveillance period.
- You will not receive any treatments or vaccines as part of this study.
- This study is being funded by the U.S. Centers for Disease Control and Prevention (CDC).

Who can be part of this study?

- Children (age <18 years) who participated in the original Prospective Assessment of COVID-19 in a Community (PACC) study and are still living in the Marshfield area.
- Being in this study is voluntary. You do not have to participate. Whether or not you join this study is completely up to you.

What will happen if I volunteer for this study?

Activities you will be asked to complete will be similar to activities you completed for the original PACC study. What you may need to do for this extension is listed in the table below.

WHAT will I have to do?	**WHEN** will I do this?	**WHERE** will I do this?	**HOW LONG** will it take?
1. Answer questions about your household, health, job/school, symptoms, and exposures.	When you agree to continue study activities and at the end of the surveillance period (April 2023)	Online or by phone	About 10-15 minutes each time
2. Answer questions about your symptoms, exposures, and vaccination status.	Every week through March 2023 and maybe longer	Online or by phone	5 minutes or less each week
3. Collect and mail in a sample from inside the front of your nose. We will give you instructions and a kit. This sample may be tested for the SARS-CoV-2, influenza, and other viruses.	When requested. We will ask you to collect a sample when you report a new COVID-19- or influenza-like illness.	At home	About 5 minutes each time
4. Come in for up to 3 study visits to provide a blood sample (about 1 tablespoon).	One visit around the end of the study period (~March-May 2023). If you receive influenza and/or COVID-19 vaccine during the study period, we may ask you to come in for an additional blood draw.	Marshfield Clinic	About 30 minutes for each visit

We estimate you will spend about **3 to 5 hours** on this study through May 2023. The actual time you spend on this study will depend on when you start the study and which activities you are requested to complete.

What happens if I have a positive test for COVID-19?

- You will be notified of your positive test result.
- We may ask you to:
  - Answer additional questions about your illness and health about 1 month after your positive test.
  - Come to the Marshfield Clinic for up to 2 additional study visits to provide a blood sample (about 1 tablespoon). The visits will take about 30 minutes and occur about 1 month and 4 months after your positive test.
- Public health authorities will be notified of your positive test and they may contact you for more information.

What potential benefits are there to participating in this study?

- If you provide a nose sample and it is tested for SARS-CoV-2 or influenza, you will get the result of that test.
- Information from this study will help public health agencies and doctors better understand COVID-19 vaccination and infection in children, and help efforts to prevent spread of the virus.

What potential risks do I face in this study?

- There are no major risks from being in this study.
- The risks of having blood drawn include some pain when the needle goes in and a small risk of bruising or swelling at the site of the blood draw. Some people get lightheaded or faint.
- As with all research, there is a chance that confidentiality could be compromised. However, we take precautions to minimize this risk.

What personal information will be used for this study?

- Study staff will use the following direct identifiers for study purposes such as to contact you and determine study eligibility: name, birth date, address, email, phone number, and medical history number.
- We may use protected health information from your medical records such as diagnoses, treatments, vaccinations, medications, procedures, laboratory results, imaging results, and conditions that may affect your protection against viruses for this study.

Who will be able to see my personal information?

- Representatives from the Institutional Review Board (IRB), whose job is to protect research subjects, and approved study staff may have access to your records. All study staff have completed required training for protection of research participants and personal information.
- Marshfield Clinic researchers may share test results, nose or blood samples, and study data with the University of Wisconsin-Madison and CDC or a designated laboratory. If these outside groups share the information it may not be covered by the HIPAA Privacy Rule.
- No directly identifying information will be shared outside the Marshfield Clinic Health System unless required for public health.

How will my health information be protected?

- Collected information will be stored in a restricted access area, or on a secure data server.
- Your authorization to use your protected health information does not expire, but you may take back your authorization by notifying us in writing at the address listed below:

  Huong McLean, PhD
  Center for Clinical Epidemiology & Population Health
  Marshfield Clinic Research Institute
  1000 N. Oak Ave, ML2
  Marshfield, WI 54449

What are my rights as a research subject?

- You may choose not to participate in this study at any time.
- If you decide not to participate, it will not affect your relationship with the Marshfield Clinic Health System in terms of treatment, payment or eligibility for benefits.
- If you have any questions about your rights as a research subject, you may contact the IRB at 1-800-782-8581, ext. 9-3022.

How will my left over samples be used?

- Your leftover nose and blood samples will be stored for use in future research. We are asking to use your medical record information along with the sample for future research. Samples and medical information are most useful for research when they are studied together.
- Researchers at Marshfield Clinic Research Institute will be allowed to use your sample and information for research only if the research has been approved by the Institutional Review Board.
- The only risk to you for taking part in this bio-bank is the slight risk that personal information that can identify you could be seen by someone not authorized by the research study. Marshfield Clinic security and confidentiality practices will control the use of your sample and information in order to decrease the chance of this happening.
- If you change your mind about taking part in the bio-bank later, you may ask that your sample and information be removed. Any samples that are not currently in use as part of an approved project will be destroyed.

Will there be any financial cost to me if I take part in this study?

- There will be no cost to you for participating in this study.
- The study will pay for any laboratory testing on the samples you provide for this study.

Will I be paid to be in this study?

- You will be paid for your time to complete study activities. For example, you would receive $170 for completing 1 blood draw and weekly surveys for 30 weeks. The amount you actually receive will depend on which study activities are completed and how long you are in the study. A check will be sent approximately monthly for activities completed. Payments include:
  - $50 after each blood draw.
  - $4 for completing each weekly illness survey.
  - $4 for collection and return of each nose sample when requested.
- Payments you receive from Marshfield Clinic for being in any and all research studies are considered income by the Internal Revenue Service. If Marshfield Clinic anticipates that the total amount of participant payments you receive will reach or exceed $600 in a calendar year, we will ask you to complete a Form W-9, which will include providing your social security number.

What if I have more questions about this study?

- If you have any questions about this study or need information at any time, please call 800-468-9700 or email pacc@marshfieldresearch.org