

Research Information Sheet

Prospective Assessment of COVID-19 in a Community Extension (PACC 2)

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.
- You were asked to join this study because you live in or near Marshfield, Wisconsin and participated in the original Prospective Assessment of COVID-19 in a Community (PACC) study. We want as many of the original study participants as possible to participate in the extension through at least April 2022.
- 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?

- People 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. <u>Answer questions</u> about your household, health, job/school, symptoms, and exposures.	Before your first visit and at the end of the study	Online or by phone	About 10-15 minutes each time
2. <u>Answer questions</u> about your symptoms, exposures, and vaccination status.	Every week through April 2022 and maybe longer	Online or by phone	5 minutes or less each week
3. <u>Collect and mail in a sample from inside the front of your nose.</u> We will give you instructions and a kit. This sample may be tested for the new coronavirus, influenza, and other viruses.	Every week through April 2022 and maybe longer	At home	About 5 minutes each time
4. <u>Come in for up to 3 study visits</u> to provide a blood sample (about 1 tablespoon).	When you begin the study, and about every 12 weeks after the first visit. The time between visits may be shorter if you receive COVID-19 vaccine or test positive for COVID-19.	Marshfield Clinic	About 30 minutes for each visit

We estimate you will spend about **2 to 3 hours** on this study through April 2022. The time you spend on this study will be longer if the follow-up (survey) period is extended and you choose to participate after April 2022.

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

- You will be notified of your positive test result.
- We will ask you to:
 - Answer additional questions about your illness and health about 1 month after your positive test.
 - Come to the Marshfield Clinic for 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 may be notified of your positive test and 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 in rural communities, and help efforts to prevent spread of the virus in rural areas.

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 protected information 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. You may receive \$196 for completing blood draws and weekly surveys with collecting nose samples for 12 weeks. The amount you 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