Research Information Sheet
Prospective Assessment of COVID-19 in a Community
Evaluation of 2022-23 Influenza Vaccination – Follow-up Blood Draw

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?
- The purpose of this study is to understand immune response to influenza vaccination by age.
- This study is being funded by the U.S. Centers for Disease Control and Prevention (CDC).

Who can be part of this study?
- Participants of the Prospective Assessment of COVID-19 in a Community (PACC) study who recently received the 2022-23 influenza vaccine.
- 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?
- Agree to have up to 10 mL of blood drawn (about 2 teaspoons).

What potential benefits are there to participating in this study?
- Information from this study might help researchers to learn more about how the immune system fights influenza.

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, 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 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 receive a mailed check for $50 after completion of the blood draw.
- 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