Research Informed Consent Summary

Prospective Assessment in a Community Cohort: Enteric and Respiratory pathogens (PACC-ER)

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Please read the following information carefully before you make a decision. Ask questions if you do not understand. Parents or legal guardians who are considering giving permission for their child to be in this study, please note: the word 'you' below refers to the person being invited to be in this study.

What is the purpose of this research study?

- This study will help researchers learn more about the germs that cause respiratory symptoms, such as 'a cold' or 'the flu,' and gastrointestinal (GI) symptoms, such as 'the stomach flu' or 'diarrhea.' Results from this study will contribute to public health planning to prevent respiratory and GI illnesses.
- Funding for this research comes from ModernaTX, Inc. (referred to as Moderna in this form).

Who can join this study?

- You are being asked to take part in this research because you live in or near Marshfield, Wisconsin.
- We want about 1500 people to join the study through Summer 2028 or sooner if funding runs out.
- Taking part in research is voluntary. You can choose not to be in this study or stop at any time.

How do I participate in the study?

If you decide to participate, you will:

- Answer questions about yourself, household, health, job/school, medical history, and behaviors when you join the study, and every summer after. (About 20 minutes each time)
- Answer questions about your symptoms weekly until Summer 2028 or sooner if the study ends early. (About 2 minutes each time)
- Collect and mail in a nose swab when you have new respiratory symptoms. (About 5 minutes each time)
- Collect and mail in a stool (poop) sample when you have new GI symptoms. (About 10 minutes each time)
- Answer questions about your respiratory or GI illness 1-2 times after each illness. (About 10 minutes each time)
- Come in for up to 5 study visits to provide a blood sample when you join the study and every summer after. Allow us to collect a saliva sample at the first study visit. Study visits are optional for children under 5 years old. (About 60 minutes for the first visit and 30 minutes each visit after)
- Allow us to access your medical record and health insurance claims to collect relevant information for this study.
- Some participants may be asked to come in for extra study visits to collect blood and/or saliva samples about 1 month after illness or vaccination. (About 30 minutes each visit)

What are the potential risks of taking part in the study?

- There are no major risks from being in this study.
- You may feel uneasy while collecting the nose swab. This may cause you to sneeze.
- 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 may get lightheaded or faint.
- There is a chance that confidentiality could be compromised. Extensive security and confidentiality procedures are used to decrease the chance of this happening.
- This research may also involve risks or discomforts that are currently not known.

What potential benefits are there to taking part in the study?

- Being in this study will not help you directly.
- This study will help us learn about the germs that cause respiratory and GI illnesses. This may help others in the future.

- We will inform you if you have influenza (flu), COVID-19, respiratory syncytial virus (RSV), or norovirus.

What personal information will be used?

- Study staff will access your medical record to collect information needed for the study including name, birth date, medical history number, phone number, address, demographics, and medical history.

Who will be able to see my personal information?

- Representatives from the Institutional Review Board (IRB), whose job is to protect research participants, and approved study staff will have access to your records. All staff have completed required training for protection of research participants and personal information.
- Marshfield Clinic Research Institute researchers may share test results, biological samples, and study data with researchers at Moderna, University of Wisconsin-Madison, and other institutions or laboratories. If these outside groups share the information, it might not be covered by the HIPAA Privacy Rule.
- You will be paid with a research debit card. The company Marshfield Clinic uses to manage research payments will need your name, birth date, address, email, and social security number so they can pay you.
- We will not share directly identifying information outside of Marshfield Clinic unless required for research payment or public health reporting.

How will my health information be protected?

- Collected information will be stored in a restricted access area or on a secure server.
- Your permission to use your protected health information does not expire, but you may cancel your permission by notifying Dr. Huong Nguyen in writing (1000 N Oak Ave, ML2, Marshfield, WI 54449).

What are my rights as a research participant?

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

How will my left-over samples be used?

- Your left-over nose swab, stool, blood, and saliva 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.
- 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 IRB.

Will there be any financial cost to me if I participate 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 for participating in the study?

- You will be paid for your time to complete study activities. If you are in the study for 4 years and complete the main study activities, you may receive between $456 and $756. You may receive extra payment if we ask you to complete extra activities. Payments include:
  - Between $2-$10 for completing surveys.
  - $2 for collection and return of each nose swab.
  - $5 for collection and return of each stool (poop) sample.
  - $50 after each blood draw.

For questions about the study, contact the study team: 800-468-9700 or pacc@marshfieldresearch.org

Research Informed Consent Form

Marshfield Clinic Research Institute

SP Code: MCL10723
PIs: Huong Nguyen and Joshua Petrie
Title: Prospective Assessment in a Community Cohort: Enteric and Respiratory pathogens (PACC-ER)
Version Date: May 21, 2026
Contact: 800-468-9700 or pacc@marshfieldresearch.org

Being in this study is voluntary. Whether or not you decide to take part in this research is completely up to you. You should read the following information carefully before you make a decision. In writing this consent form, some technical words were necessary. Please ask for an explanation of anything you do not understand. Ask study staff as many questions as you wish about this consent form and what will happen to you as part of this research. Parents or legal guardians who are considering giving permission for their child to be in this study, please note: the word 'you' below refers to the person being invited to be in this study.

Introduction and Purpose of Study

You are being invited to take part in a research study conducted by Marshfield Clinic Research Institute. You have been asked to participate in this research because you live in or near Marshfield, Wisconsin. People commonly get sick with respiratory symptoms, such as 'a cold' or 'the flu,' and gastrointestinal (GI) symptoms, such as 'the stomach flu' or 'diarrhea.' The purpose of this study is to learn more about the germs that cause these respiratory and GI symptoms. Results from this study will help us better understand the importance of respiratory and GI illnesses. We want about 1500 people to join the study through Summer 2028, or sooner if funding runs out.

Study Plan

If you volunteer for this study, you will be asked to do the following things:

Study Activities	**WHEN** will I do this?	**WHERE** will I do this?	**HOW LONG** will it take?
1. Answer questions about yourself, household, health, job/school, medical history, and behaviors.	• When you join the study • Every summer after you join the study	In person, by phone, or online	About 20 minutes each time
2. Answer questions about your symptoms.	▪ Once a week for the time you are in the study	Online or by phone	About 2 minutes or less each week
3. Answer questions about your illness.	• Each time you report new respiratory or GI symptoms • 1-2 times after each illness	Online or by phone	About 10 minutes or less for each survey
4. Collect and mail in a sample from your nose. We will give you instructions and a kit.	• When we ask for a nose swab, usually when you have new respiratory symptoms	At home	About 5 minutes each time
5. Collect and mail in a stool (poop) sample. We will give you instructions and a kit.	• When we ask for a poop sample, usually when you have new GI symptoms	At home	About 10 minutes each time

Study Activities	**WHEN** will I do this?	**WHERE** will I do this?	**HOW LONG** will it take?
6. Come in for up to 5 study visits to provide a blood sample (about 4 teaspoons or less each time). We may collect a saliva sample at the first visit. Study visits are optional for children under 5 years old.	• When you join the study • Every summer after you join the study	Marshfield Clinic	About 60 minutes for the first visit and 30-45 minutes for the other visits
7. If we ask you to, come in for extra study visits after an illness or after you get vaccinated to provide a blood sample and/or saliva sample	• When we ask you to come in, usually about 1 month after an illness or vaccination	Marshfield Clinic	About 30 minutes for each visit

We will also access your medical records and health insurance claims to collect relevant information for this study.

We estimate you will spend between **12 and 30 hours** total on this study. The time you spend on the study will depend on how long you are in the study and the activities we ask you to complete. The time you spend may be longer if you have more episodes of respiratory or GI symptoms during the study period.

Potential Risks and Discomforts

- There are no major risks from being in this study.
- You may feel uneasy while collecting the sample from your nose. This may cause you to sneeze.
- 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.
- We will collect information about you in this study. There is a risk that some of your information could be accessed by someone not authorized by the research study. However, Marshfield Clinic is committed to protecting your privacy. We have extensive security and confidentiality procedures to decrease the chance of this happening.
- This research may also involve risks or discomforts that are currently not known.

Potential Benefits to Subjects

- Being in this study will not help you directly. But this study will help us learn more about the germs that cause respiratory and GI illnesses. This may help others in the future.
- You will find out if you have influenza, COVID-19, respiratory syncytial virus (RSV), or norovirus. The research tests are not intended to replace tests your health care provider may order for you. If you are concerned about your symptoms, health, or exposure, please contact your health care provider.

Alternatives to this Study

You do not have to be in this study if you do not want to. If you decide not to participate, it will not affect your relationship with Marshfield Clinic in terms of treatment, payment, or eligibility for benefits.

Sample Storage for Future Research

As part of this study, we may collect respiratory (nose swab), stool, saliva, and blood samples for research testing. After those tests are done, there may be samples left over. We will store leftover samples for use in future research. We may access your medical record information 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 and Moderna will only be allowed to use your sample and information for research if their research is approved by the Institutional Review Board.

The only risk to you for taking part in this sample storage is the slight risk that your identifiable information could be accessed by someone not authorized by the research study. However, Marshfield Clinic security and confidentiality practices will control the use of your samples and information to decrease the chance of this happening.

If you change your mind about taking part in this sample storage, you may ask that your samples and information be removed. Any samples that are not currently in use as part of an approved project will be destroyed.

Cost for Participation

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

Payment for Participation

You will be paid for your time to complete study activities. The amount you receive will depend on the length of time you are in the study and the activities we ask you to complete. If you are in the study for 4 years and complete the main study activities, you may receive between $456 and $756. You may receive extra payment, with the amount dependent on the number of samples we ask you to collect, the number of extra surveys you complete, and the number of extra visits we ask you to complete after an illness or vaccination. Payments include:

- $10 after completing the enrollment survey.
- $2 for completing each weekly survey. Payment will be sent about every 3 months.
- $2 for collection and return of each nose swab when we ask you to collect a sample. Payment will be sent about every 3 months.
- $5 for collection and return of each stool (poop) sample when we ask you to collect a sample. Payment will be sent about every 3 months.
- $5 for completing each follow-up illness survey. Payment will be sent about every 3 months.
- $50 after each blood draw. Payment will be sent after the visit is completed.
- $5 for completing each summer survey. Payment will be sent about every 3 months.

Payment for completing study activities will be put on a debit card for research (physical or electronic) according to the schedule described above. You will be given one card to use for the whole time you participate in this study.

In order to be paid with the debit card, we will need to share information about you with the company Marshfield Clinic uses to manage research payments. This will include your name, birth date, address, email, and social security number. There are security safeguards to protect your personal information. Your personal information will not be shared by the payment company, sold, or used for any other purpose. Your information will be kept for as long as necessary to make your payments and to follow applicable laws.

When you register and use the debit card, you are agreeing to participate in the debit card program. If you choose not to take part in the debit card program, you may still participate without being paid.

Data or Sample Sharing

The information and samples you give may be shared with researchers at Moderna, researchers at the University of Wisconsin-Madison, and other designated researchers or laboratories. We will not share your name, address, phone number, or any other information that could directly identify you with Moderna, the University of Wisconsin-Madison, or other researchers or laboratories. For the purpose of data analysis, the information and samples you provide for this study may be shared with other similar research studies you join at Marshfield Clinic Research Institute.

Authorization (Permission) to Use or Disclose (Release) Protected Health Information for Research

Researchers at Marshfield Clinic Research Institute are required by HIPAA, the federal privacy law, and other state privacy laws, to get permission to use and/or release identifiable health information from you for research purposes.

If you agree to take part in this research study, you agree to provide permission to use and/or release your identifiable health information for research purposes.

What personal health information will be used, and for what purpose?

Marshfield Clinic Research Institute researchers want to use portions of your medical record for this research.

The types of identifiable health information that may be used by Marshfield Clinic Research Institute researchers include the following:

- Dates including, but not limited to birth date, medical care dates, immunization dates, laboratory test dates, and diagnosis dates.
- Medical history needed for this study. This may include your diagnoses, physical exam findings, laboratory results, medical procedures, medications, and other relevant information.
- Name, address, email, and phone number (for contacting you for study purposes).

What personal health information will be disclosed, and for what purpose?

Your identifiable health information may be shared with external groups responsible for research regulations. This includes institutional review boards (IRBs) or privacy boards who review studies, or government agencies including the Food and Drug Administration (FDA) and Office of Human Research Protection (OHRP), for review or audit purposes.

Researchers may also share health information collected or created about you as necessary in the performance of the research. The persons and entities receiving your health information, the type of health information to be shared, and the purposes for the disclosure, are listed below:

Persons	Entity	Information to be Shared	Purpose
Researchers	Moderna and other designated researchers or laboratories	Unique code number for this study, medical history, demographic information, and other data collected in this study	To analyze data and biological samples and interpret results
Researchers	University of Wisconsin-Madison	Unique code number for this study, medical history, demographic information, and other data collected in this study	To analyze data and biological samples and interpret results
Employees who manage research payments	Suvoda or the company Marshfield Clinic contracts to manage research payments	Name, birth date, address, email, social security number	To make payments for participating in this research study

The privacy and confidentiality of your information is important to us. We will remove as many identifiers as possible. Only the minimum amount of identifiable health information needed to accomplish the research purposes will be shared. We will not share directly identifying information, such as name, address, or phone number, outside Marshfield Clinic unless required for research payment or public health reporting.

If your health information is shared with research collaborators outside of Marshfield Clinic who are not regulated by the HIPAA privacy law or other state privacy laws, we cannot guarantee that the information we share with others will be protected by the same rules.

How long will my permission last, and can I change my mind?

Your permission to use and/or share your health information for this research does not have an end date. You may take back your permission at any time, but you will have to do so in writing. Your cancelled permission will not apply to information that researchers already shared or used before you took back your permission. After your permission ends, no new health information will be collected, used, or shared. If you take back your permission, you can no longer take part in this research.

To take back your permission, notify Dr. Huong Nguyen (1000 N Oak Ave, ML2, Marshfield, WI 54449) in writing.

Giving your permission to use and/or share your information for this research is voluntary. You do not have to give permission, and you may refuse to do so. If you do not give your permission, it will not affect your:

- Current or future health care at Marshfield Clinic.
- Current or future payments to Marshfield Clinic.
- Ability to enroll in any health plans.
- Eligibility for benefits.

Confidentiality

Your medical, hospital, or other billing records and research material that would identify you will be held confidential and protected by Marshfield Clinic confidential policies. Medical records that identify you, the consent form, and any other study information may be inspected by the following agencies:

- *Researchers at Moderna or their designees*
- *Marshfield Clinic Research Institute's Institutional Review Board*
- *Governmental regulatory (or health) agencies*
- *Medical professionals who need to access your medical record for your continuing care*

Because of the need to release pertinent sections of information to these parties, all efforts will be made to maintain confidentiality. These people must also keep the information confidential. Your name will not be given to anyone not associated with the study unless required by law or research payment.

The results of this study may be presented at scientific meetings or in scientific publications; however, your identity will not be disclosed.

Identifiers might be removed from your private information or biological samples. After identifiers are removed, your information or biological samples could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

New Findings

You will be told of any new findings regarding this research that may affect your willingness to be in this study.

Study Results. If your nose swab tests positive for influenza, SARS-CoV-2 (COVID-19), or RSV or your stool sample tests positive for norovirus, we will share the result with you and record the result in your medical record. Results of other research testing WILL NOT be provided to you or placed in your medical record. The Clinical Laboratory Improvement Act (CLIA) of 1998 prohibits laboratories from providing the results of research-only tests to research participants or their doctors.

Withdrawal from the Study

You may change your mind about taking part in this research at any time. You may withdraw your consent for all or part of the research. If you decide to leave the study, please let study staff know. If you decide to stop taking part in this study after you give information or samples to us, we will continue to use the information and samples that were collected before your decision not to be in the study.

Termination from Study

Participation in the study may stop if the following occurs:

- *The sponsor, for administrative reasons, decides to take you off or terminate the study*
- *You do not follow study instructions or refuse to complete study procedures*
- *You move out of the study area*

If we withdraw you from the study, we will notify you and continue to use the information and samples that were collected before you were withdrawn.

Electronic Communication for Research

Marshfield Clinic Research Institute or its researchers may use electronic communication including email/and or text messaging to communicate with you about research participation. If you agree to participate in this study, you give permission for researchers to use electronic means to communicate with you regarding any and all research studies in which you enroll. Pursuant to federal regulation (16 CFR 312), research participants, ages 12 years and under, cannot utilize electronic communication. Pursuant to the same regulation, and with parent/legal guardian consent, research participants ages 13 through 17 years can use electronic communication. As the parent/legal guardian of the research participant, you consent to the collection, use, and/or disclosure of your, and the aged 13-17 years individual's, online contact information.

If you agree to participate in this study, you acknowledge that you understand each of the following:

- Electronic communication is not secure when sent, nor when they are stored or viewed on a personal electronic device.
- Because electronic communication is not secure, it could be lost or read by someone else without the knowledge of researchers.
- Researchers cannot use electronic communication to diagnose or treat illness.
- Researchers cannot use electronic communication to communicate with you about emergencies or urgent issues.
- Researchers cannot guarantee an answer to your electronic communication within a certain timeframe.
- Marshfield Clinic Research Institute cannot guarantee that electronic communication will be free from technical difficulties, such as loss of messages.
- Marshfield Clinic Research Institute has the right to refuse electronic communication with you or to terminate electronic communication with you for any reason and at any time.
- Use electronic communication for communicating non-sensitive information only. If you wish to discuss highly sensitive information with researchers, please use a secure means of communication.
- Your consent for electronic communication is valid until you notify a Marshfield Clinic Research Institute researcher in writing that you withdraw your permission.

Electronic communication is insecure. If you agree to participate in this study, you accept all risk of loss of privacy or confidentiality associated with use of electronic communication. Marshfield Clinic Health System, Marshfield Clinic, Inc., and Marshfield Clinic Research Institute are not responsible for any type of damage or liability arising from, or associated with, loss of privacy or confidentiality due to electronic communication.

Study Contacts

For more information about this research or to report problems, you may contact the study team at pacc@marshfieldresearch.org or 800-468-9700.

Rights of Research Subjects

Being in this study is voluntary. Refusing to participate or stopping participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate in this research, your relationship with your doctor and this institution will not change.

You are not giving up any legal rights by taking part in this research study.

If you have any questions about your rights as a research participant, you may contact Marshfield Clinic Research Institute's IRB at 1-800-782-8581 ext. 9-3022. The IRB is responsible for helping protect rights and welfare of human research participants. You may also call this number to discuss problems and concerns, to request information or ask questions, and to offer input.

Signing the Consent

A signature indicates that:

- You have read this form which includes a description of how your health information will be used and shared.
- You have had a chance to ask questions including about the use of your health information, and you have received answers to your questions.
- You agree to the use and release of all your health information that may be created or collected for the research study.
- You have freely decided to take part in the research study described above.
- The study's general purposes, details of involvement and possible risks and discomforts have been explained to you.

You will receive a signed copy of this consent form.

Signatory Type

- ❑ Participant
- ❑ Parent of Minor Participant
- ❑ Legal Guardian of Minor Participant

_____
Printed Name of Participant

_____
Printed Name of Signatory (if different from participant)

_____
Signature of <Signatory Type>

_____
Date of Signature

_____
Printed Name of Presenter

_____
Signature of Presenter

_____
Date of Signature

07/24/24; 04/08/25, 08/08/25; 05/21/26
H:\Radmin\ORIP\IRB\Consent Documents\Consent Forms\I-M\CF_MCL10723_1.docx
See Also: H:\Radmin\ORIP\IRB\Consent Documents\Consent Forms\I-M\CF_MCL10723_2 Assent.docx