Research Informed Consent Summary (Version 2.0)

Surveillance Platform for Acute Illness: Respiratory and Enteric Pathogens (inSPIRE)

Marshfield Clinic Research Institute | PI: Joshua Petrie, PhD | PET40823
877-905-4053 | inspirestudy@marshfieldresearch.org

You are being asked to take part in this research because you sought medical care for an illness with new or worsening respiratory and/or gastrointestinal (GI) symptoms that began less than 10 days ago. Parents, legal guardians, or other authorized representatives who are considering giving permission for someone else 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 and GI illnesses.
- Funding for this research comes from ModernaTX, Inc. (referred to as Moderna in this form).

How do I participate in the study?

If you decide to participate, you will:

- Answer questions about yourself and your illness symptoms, general health, and immunization history today.
- **If you have respiratory symptoms**, we will collect a nose swab and a throat swab (nose swab only for children under 2 years old).
- **If you have GI symptoms**, you will collect a stool sample and return it to us. We will give you supplies and instructions.
- Complete 2 follow up surveys about your illness, one in about 2 weeks and one in about a month.
- Allow us to access your medical record and health insurance claims to collect relevant information for this study.
- Allow us to use your leftover samples from the hospital laboratory that were collected as part of your medical care for this illness.
- Some people will be invited to give blood samples at up to 2 time points: shortly after enrollment and/or in about a month. The total amount of blood collected from you during this research study will be around 40 mL or less, which is about 8 teaspoons. Not everyone will be invited to give these samples. You do not have to give these samples to take part in the study.

What potential benefits are there to participating in this 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.

What potential risks do I face in this study?

- There are no major risks from being in this study.
- If you have respiratory symptoms, the nose and throat swabs might be briefly uncomfortable.
- If you give a blood sample, 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.
- As with all research, 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 presently not known.

What personal information will be used?

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

Who will be able to see my personal information?

- Approved study staff will have access to your records. All staff members have completed required training for protection of research participants and personal information.

- Representatives from the Institutional Review Board (IRB) may have access to your records. It is the job of the IRB to protect research participants.
- Marshfield Clinic researchers may share test results, laboratory samples, and study data with researchers at Moderna, researchers at the University of Wisconsin-Madison, and other researchers or laboratories. We will not share your name, address, phone number, or any other information that could directly identify you with Moderna, University of Wisconsin-Madison, or other researchers or laboratories.
- Data from this study may be used to determine eligibility for other similar studies conducted by Marshfield Clinic Research Institute.
- You may be paid with a Greenphire ClinCard. Greenphire is a company Marshfield Clinic Health System uses to manage research payments. If you receive a ClinCard, we will share your name, date of birth, address, email, and social security number with Greenphire so they can pay you.
- We will not share directly identifying information, such as name, address, or phone number outside the Marshfield Clinic Health System unless required for research payment or public health reporting.
- If your data is shared outside the Marshfield Clinic Health System, it might not be covered by the HIPAA Privacy Rule.

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 at any time by notifying Joshua Petrie, PhD in writing (1000 N Oak Ave, ML2, Marshfield, WI 54449). Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your permission.

What are my rights as a research participant?

- Your participation is completely voluntary. You may choose not to participate in the study at any time.
- If you decide to not participate, it will not affect your relationship with Marshfield Clinic Health System 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.

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 samples you provide for this study.

Will I be paid for participating in the study?

- If you have respiratory symptoms, you will receive $35 after we collect the nose and throat swabs. If you only have GI symptoms, you will receive $35 after we receive your stool sample.
- If you give a blood sample, you will receive $50 for each blood sample given.

Will my study test results be shared with me?

- If you have respiratory symptoms, your nose and throat swabs will be tested for common germs that cause respiratory illness. The results of tests for influenza, SARS-CoV-2 (COVID-19), and RSV will be shared with you and recorded in your medical record.
- Results of other research study tests will not be shared with you.
- These research tests are not intended to replace tests your healthcare provider may order for you.
- The results of these research tests will take longer than tests your healthcare provider may order for you.
- Please contact your healthcare provider if you have questions or concerns about your symptoms, health, exposure, or study test results.

What if I have more questions about the study?

- If you have any questions or need information, please call 877-905-4053.

Research Informed Consent Form (Version 2.0)

Marshfield Clinic Research Institute

SP Code: PET40823
PI: Joshua Petrie, PhD
Title: Surveillance Platform for Acute Illness: Respiratory and Enteric Pathogens (inSPIRE)
Contact: 877-905-4053 | inspirestudy@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. Some technical words were needed to write this consent form. 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, legal guardians, or other authorized representatives who are considering giving permission for someone else to be in this study, please note: in the sections that follow, the word 'you' refers to the person being invited to be in this study.

Introduction and Purpose of Study

You are invited to take part in a research study conducted by the Marshfield Clinic Research Institute. This research is being funded by Moderna.

Respiratory illnesses (for example: 'a cold' or 'the flu') and gastrointestinal (GI) illnesses (for example: 'the stomach flu' or 'diarrhea') are a common reason for people to need medical care. These illnesses can be caused by many different germs including viruses, bacteria, and parasites. In this research study, we want to find out how often different germs cause respiratory and GI illnesses. We also want to find out about the symptoms and severity of these illnesses.

You are being asked to take part in this research because you sought medical care for an illness with new or worsening respiratory and/or GI symptoms that began less than 10 days ago.

Study Plan

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

- Answer questions about yourself and your illness symptoms, general health, and immunization history today.
- **If you have respiratory symptoms**, we will collect a nose swab and a throat swab (nose swab only for children under 2 years old).
- **If you have GI symptoms**, you will collect a stool sample and return it to us. We will give you supplies and instructions.
- Complete 2 follow up surveys about your illness, one in about 2 weeks and one in about a month.
- Allow us to access your medical record and health insurance claims (if you are a Security Health Plan member) to collect relevant information for this study.
- Allow us to use your leftover blood, stool, or respiratory samples from the hospital laboratory that were collected as part of your medical care for this illness.

You may also be invited to give blood samples at up to 2 time points: shortly after enrollment and/or in about a month. Not everyone will be invited to give these samples. You do not have to give these samples to take part in the study. If you give these samples we will collect 20 mL of blood or less during each blood draw, which is about 4 teaspoons. If you give blood two times, you would have up to a total of 40 mL of blood (about 8 teaspoons) collected as part of this study.

This research study is expected to enroll about 9,500 people. Your participation will take about 40 minutes: about 20 minutes to complete an enrollment interview and collect nose and throat swabs and/or stool samples, 10 minutes in about 2 weeks, and 10 minutes in about a month. If you give blood samples it will take about an extra 30 minutes shortly after enrollment and/or about 30 minutes in about a month.

Potential Risks and Discomforts

- There are no major risks from being in this study.
- If you have respiratory symptoms, the nose and throat swabs might be briefly uncomfortable.
- If you give a blood sample, 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.
- 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 Health System is committed to protecting your privacy. Extensive security and confidentiality procedures are used to decrease the chance of this happening.
- This research may also involve risks or discomforts that are presently not known.

Potential Benefits to Participants

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.

Alternatives to this Study

You do not have to be in this study if you do not want to. Your usual health care will not change whether you do or do not participate.

Sample Storage for Future Research

As part of this study, we may collect respiratory (nose or throat swabs), stool, 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 samples 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 samples and information 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 Health System 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. The study will not pay for charges related to tests ordered by your healthcare provider for clinical care. You or your insurance company will be responsible for those charges.

Payment for Participation

You will receive a $35 gift card for participating in this research study. If you have respiratory symptoms, the gift card will be given to you after we collect the nose and throat swabs. If you have only GI symptoms, the gift card will be given to you after we receive your stool sample.

If you are invited and give a blood sample, you will receive $50 for each blood sample given. Payments for blood samples, as well as the $35 payment for giving nose and throat swabs and/or a stool sample, will be made with a Greenphire ClinCard.

Greenphire is a company used by Marshfield Clinic Health System to manage research payments. You will be given a Greenphire ClinCard debit card (physical or electronic). Payment for each study activity will be put on the debit card after you complete the activity. You will be given one card to use for the whole time you participate in this study.

In order for Greenphire to be able to pay you with the ClinCard, study staff will need to share information about you with Greenphire. This will include your name, date of birth, address, email, and social security number. Greenphire has security safeguards to protect your personal information. Your personal information will not be shared or sold by Greenphire. Greenphire will only use your information to manage payments. Your information will be kept by Greenphire for as long as necessary to make your payments and to follow applicable laws.

When you register and use the ClinCard, you are agreeing to participate in the ClinCard program. Please be sure to read the instructions that come with the ClinCard. If you choose not to take part in the ClinCard program, you may still participate without being paid.

Payments that you receive from Marshfield Clinic Health System for participating in any and all research studies are considered income by the IRS. If Marshfield Clinic Health System thinks that you will receive $600 or more in total research payments in a calendar year, you will be asked to complete a Form W-9. This includes providing your social security number. If you receive $600 or more in total research payments, you will be given an IRS Form 1099-MISC by January 31 of the following year. Reportable payment types may include, but are not limited to: checks, gift cards, personal property, and other items of value. No taxes are withheld from your payments. That means you are responsible for paying any applicable state, federal, Social Security, or other taxes on the payments you receive. Please note that Marshfield Clinic Health System follows procedures to make sure research payments are reported following state and federal income reporting requirements.

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. Data from this study may be used to see if you are eligible for other similar research being done 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 includes 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(s)	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	Greenphire	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 the Marshfield Clinic Health System unless required for research payment or public health reporting.

If your health information is shared with research collaborators outside of the Marshfield Clinic Health System 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, write a note stating this decision and send it to:

Joshua Petrie
Center for Clinical Epidemiology and Population Health
1000 N Oak Ave, ML2
Marshfield, WI 54449

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 Health System.
- Current or future payments to Marshfield Clinic Health System.
- 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 Health System policies. Medical records that identify you, the consent form, and any other study information may be inspected by:

- Marshfield Clinic Research Institute's Institutional Review Board.

- Researchers at Moderna or their designees.
- Other 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 for 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 researcher for future research studies without additional informed consent.

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

If you have respiratory symptoms, your nose and throat swabs will be tested for common germs that cause respiratory illness using an approved diagnostic test. The results of tests for influenza, SARS-CoV-2 (COVID-19), and RSV will be recorded in your medical record. You can view the results through your My Marshfield Clinic account (website or mobile app). We will also test your nose and throat swabs for other germs that cause respiratory illness, but the results of these tests WILL NOT be provided to you or placed in your medical record.

Results from research testing of your stool or blood samples 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.

These research tests are not intended to replace tests your healthcare provider may order for you. The results of these research tests will take longer than tests your healthcare provider may order for you. Please contact your health care provider if you have questions or concerns about your symptoms, health, exposure, or study test results.

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 the researchers 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 given up until the decision not to be in the study.

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 inspirestudy@marshfieldresearch.org or 1-877-905-4053.

Rights of Research Study Participants
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 Institutional Review Board (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.

Please do not sign this form if your name is spelled incorrectly.

Signatory Type

- ❑ Participant
- ❑ Adult Participant's Legal Guardian
- ❑ Adult Participant's Activated Power of Attorney for Healthcare
- ❑ Minor Participant's Parent
- ❑ Minor Participant's Legal Guardian

_____
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 Presented