Clinical Research
Patient Information

MNGI's Clinical Research Team is led by Dr. Ibrahim Hanouneh. Our team includes experienced gastrointestinal doctors, physician assistants, nurse practitioners, research coordinators, and research assistants. We focus on running studies safely and ethically. Our goal is to discover treatments that can help improve your digestive health and your quality of life.

MNGI Digestive Health works on studies on digestive problems. When you participate, you'll get regular medical care and be monitored closely to ensure your safety, well-being, and rights are always protected.

This packet is here to help you understand what's involved if you are thinking about being in a clinical research study at MNGI Digestive Health. It provides basic information about clinical research and what participation entails.

What is a Clinical Study?
A clinical study is done to learn more about different health conditions. One kind of clinical study is called a clinical trial.

In a clinical trial, people that volunteer get a new treatment, device, or medical procedure. The trial is a carefully planned test to see how well the treatment works and make sure it's safe.

Why do People Participate in a Clinical Trial?
Many people join a clinical trial to get access to treatments they can't normally receive, or to be treated by top doctors. Others do it to help improve medical knowledge for now and the future.

Who Can Participate in a Clinical Trial?
Every clinical trial has certain guidelines that explain who can take part. Using information like your medications, symptoms, and medical history helps us know if you might qualify to join a clinical trial.

What if I decide I don't Want to Participate?
Participation in a clinical trial is voluntary. You do not have to participate, and you are free to stop at any time.

No matter what you decide, your general care at MNGI Digestive Health will not be impacted.

Do Research Patients Have Rights?

Yes. Everyone that joins a clinical trial has rights that are meant to protect them during the trial. If you participate in a research trial, you have the right to:

- A statement that the study involves research.
- An explanation of the purpose of the research.
- Expected duration of your participation.
- A description and expected time commitment of each visit throughout the study.
- An explanation of the procedures to be followed.
- A description of any foreseeable risks or discomforts.
- A description of any benefits that may be reasonably expected.
- A disclosure of appropriate alternative procedures or medications.
- Possible risks of you not disclosing all medical history to research staff.
- A statement regarding the importance of notifying research staff of changes in medications or medical conditions.
- A statement that your medical records may be examined by the sponsor and the FDA; and if so, the extent to which those records will be kept confidential.
- An explanation as to whether any compensation and medical treatments are available if injury occurs.
- An explanation of whom to contact for answers regarding your rights, study information, and research related injuries.
- An explanation that participation is voluntary, and that you may discontinue participation at any time without loss of benefits or prejudice.
- Receive a copy of the informed consent form.

How are Research Participants Protected?

The Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) is the federal agency responsible for overseeing food, drug, and cosmetic sales in the United States. The FDA oversees the conduct of clinical studies and has put several guidelines in place to protect research volunteers.

Institutional Review Boards (IRB)

An IRB is made up of doctors, researchers, and members of the community. The purpose of an IRB is to ensure that we are protecting your rights, well-being, and safety.

The Principal Investigator (PI)

The Principal Investigator is the leader of the study team at the site. They are a medical provider who is responsible for overseeing the study activities. You will meet with the PI or another medical provider during the study for exams and to talk about how you are doing.

The Clinical Research Coordinator

The Clinical Research Coordinator provides you with the information you should know about the study. They are responsible for making sure the day-to-day study activities are being done safely. Your primary contact for all questions about the study is the Clinical Research Coordinator.

What is the Informed Consent Process?

Informed consent is a process that involves learning important information about a clinical trial before deciding if you want to participate. You will receive a document called an **Informed Consent Form**. This document will explain things such as why we are doing the study, the treatment you will get during the study, what will happen during your visits, if there are any potential risks and benefits to being in the study, if there are other treatment options for you, and how we will keep your information private.

We encourage you to take time to review the informed consent form, share the information with others involved in your medical care, and ask the MNGI Research Team any questions you have about the study and your participation.

What Happens at a Study Visit?

At each study visit, you will meet with members of the MNGI Research Team. They will complete study procedures, give you the study treatment, check on how you are feeling by reviewing your medications and any new symptoms you are experiencing, make sure you want to continue being in the study, and answer any questions you may have.

Each clinical trial requires different procedures which may include physical exams; measurements of your blood pressure, pulse, height, and weight; completion of questionnaires; lab draws. There may be additional testing ordered by the research provider to check on your general health and well-being.

Other Questions to Ask

Here are some other questions to ask the Research Team that might help you decide if you want to take part in a clinical study:

- What is the purpose of the study?
- How long is the study?
- Why do researchers think the study may be effective?
- Who has reviewed and approved the study?
- How is safety of participants being monitored?
- What are my responsibilities if I participate?
- What is the potential benefit to participating?
- What are the possible short-term and possible long-term benefits?
- Are there potential risks involved?
- What other options do I have? How do the possible risks and potential benefits of the study compare with my other options?
- Will I be able to take my regular medications during the study?
- How could being in the study affect my daily life?
- Is there any cost to me for participating in the study?
- Will I receive compensation for being in the Study?
- How many times will I visit the clinic for the study? How long will the visits be?
- What will I need to document outside the clinic while I am in the study?
- Can I talk to other people about the study?

Contact Information

MNGI Digestive Health, P.A.
Clinical Research Department – Northeast Minneapolis
3001 Broadway Street NE
Suite 120
Minneapolis, MN 55413

MNGI Digestive Health, P.A.
Clinical Research Department – Plymouth
15700 37th Avenue North
Suite 300
Plymouth, MN 55446

Clinical Research Manager	Amanda Devers	612-870-5595
Clinical Research Coordinators	Jennifer Burdick	612-870-5594
	Liban Mohamed	651-444-4314
	Naomi Mugarura	612-870-5587
	Raghd (Rudy) Qamhiyeh	651-444-0817

Research Hotline	612-870-5599
E-mail	research@mngi.com
Website	https://www.mngi.com/care-services/clinical-studies