Clinical Research

Patient Information

Led by Dr. Ibrahim Hanouneh, the MNGI Clinical Research Team is comprised of highly trained and experienced gastroenterologists, physician assistants, nurse practitioners, Clinical Research Coordinators, and Research Assistants. The Team is dedicated to conducting safe and ethical clinical research; we are committed to exploring new therapies and treatments that can potentially improve our patients' gastrointestinal health and quality of life.

MNGI Digestive Health participates in and leads studies that target conditions of the upper and lower GI tract. Throughout the study process, our patient participants are provided with consistent, comprehensive medical care and are closely monitored to ensure their safety, welfare, and rights are protected during the study.

This packet is meant to help prepare you for possible participation in a clinical research study at MNGI Digestive Health by providing information about general information about clinical research and the aspects of participation.

What is a Clinical Study?
Intended to advance medical knowledge, a clinical study involves human volunteers (often called participants). One type of clinical study is a clinical trial.

In a clinical trial, the participants receive a medical intervention such as a medication, a device, or a new procedure. A clinical trial is a controlled study of that medical intervention.

Why do People Participate in a Clinical Trial?

Many people choose to participate in a clinical study to gain access to treatments that are not otherwise available, or to receive treatments from doctors who are leaders in their field. Others participate simply to contribute to present and future medical knowledge.

Who Can Participate in a Clinical Trial?
Each clinical trial has specific criteria that identifies the type of individual that is eligible to participate. Based on medical information (such as your current medications, symptoms, and medical diagnoses) provided by you and your provider, we determine your eligibility for 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 withdraw from a clinical research trial at any time.

If you decide not to participate, or, if you are currently enrolled in a clinical trial but decide to withdraw from participation, your general care at MNGI Digestive Health will not be impacted.

Do Research Participants Have Rights?
Yes. All research participants have rights that are meant to protect them during participation in a clinical 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 the regulation of 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 steps are taken to protect the rights, welfare, and safety of research participants. The IRB reviews the research plan before a study is allowed to begin and then conducts periodic reviews during the study.

The Principal Investigator (PI)
The Principal Investigator is the leader of the study team at the site. He/she/they is the medical provider responsible for overseeing the ethical conduct at the research site and ensuring the study participants rights, welfare, and safety is protected. Research participants will meet with the PI or his/her/their colleague during the study for exams, medical discussions, and safety assessments.

The Clinical Research Coordinator
The Clinical Research Coordinator provides information to patients, reviews the informed consent form with the patient, conducts various study procedures, and maintains all medical records and other study files. He/she/they are responsible for ensuring the day-to-day study activities meets regulatory, safety, and ethical requirements. The patient's 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 study before deciding whether or not to participate. This process continues throughout the study period and is meant to keep you informed of all information about the study. Any new information that becomes available during the study will be shared with you.

You will receive a document called an **Informed Consent Form**. This document will explain why we are conducting the study, the treatment and/or therapy involved, visit procedures and requirements, potential risks and benefits, alternative treatments to participating, confidentiality of participant records, study costs and compensation, as well as study contacts.

If you decide to participate in the study, we will ask you to document your consent by signing the consent form at your first study visit. Signing the consent form simply indicates your understanding of the study and its procedures; it is not a contract obligating you to complete the study. 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, administer study treatment or therapies, check your health status by reviewing your medications and any new symptoms you are experiencing, confirm your ongoing consent, and answer any questions you may have.

Each clinical trial requires different procedures which may include (but is not limited to): physical exams; measurements of your blood pressure, pulse, height, and weight; completion of questionnaires; lab draws; ultrasounds.

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 Participating 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

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