FOR POTENTIAL PARTICIPANTS

# [redacted] CLINICAL TRIAL PATIENT INFORMATION GUIDE

## THE PURPOSE OF CLINICAL TRIALS

Clinical trials aim to answer specific questions about how medicines work in the volunteers who take them. You should feel fully informed about what to expect from your participation in a clinical trial.

Researchers use clinical trials to:

- Learn about the safety and effects of investigational medicines
- Help find new ways of using certain medications
- Answer specific health questions

All clinical trials are:

- Developed to protect the rights, safety, and well-being of participants
- Conducted according to strict scientific and ethical principles
- Reviewed and approved by an institutional review board (IRB) or ethics committee (EC)

The [redacted] Clinical Trial is a phase 2 trial, which means that the investigational medicine has already been tested for general safety. However, before the investigational medicine may be submitted for approval to use outside of clinical trials, it needs to undergo more research. In this trial, the investigational medicine is being tested for continuous safety and its effectiveness (how well it works).

**Even though you will be receiving care from the trial team, you should still see your regular doctor(s) as normal if you take part in this trial. It is important that your doctor(s) are informed of your participation when seeing you, as it could impact your medical care and treatment decisions.**

## THE IMPORTANCE OF INFORMED CONSENT

The patient information and consent form is a document provided to you that explains what it means to join this trial. It provides in-depth details about trial participation and clinical research. Your health is important to you, so it is just as important to know everything about a clinical trial before joining.

The patient information and consent form covers:

- The purpose of the clinical trial
- Information about the investigational medicine
- The visit schedule
- Test and procedure details
- Information about your data privacy
- Possible side effects, risks, and benefits
- Alternative treatment options
- Your responsibilities as a participant
- Compensation details (as applicable)

You are in full control of your healthcare decisions. It is important to discuss and ask any questions you have about the trial and clinical research so that you feel you understand what you are consenting to.

## YOUR DATA PRIVACY

When you take part in a clinical research trial, you will sign an agreement to share your personal health records and data that can identify you to the trial team.

Information shared may include your:

- First and last name
- Address
- Telephone number
- Medical records

In order to conduct and oversee the research in this trial, access to your medical records will be given to the sponsor of the trial, auditors, an ethical review board, and a regulatory health authority. When you sign the patient information and consent form, you are agreeing to this access.

Although absolute confidentiality cannot be guaranteed, your personal data will be protected by all applicable laws and regulations, and every organization that has access to your data is obliged to keep your personal information confidential.

## ABOUT THE SPONSOR

The sponsor of this trial (the organization that designed the trial and is funding and conducting research) is [redacted]

If you have any questions or concerns at any point throughout your participation, you can speak with any trial team member at your site.

## [redacted] CLINICAL TRIAL REMINDERS

If you enroll in this trial, you will be asked to:

- Not take part in any other clinical trials
- Ask your trial doctor if you have any questions
- Not take any new medications unless the trial doctor has approved for you to take them beforehand (includes all prescription drugs, over-the-counter medications, vitamins, herbal supplements, vaccines, and other kinds of therapies)
- Do not stop taking any medications without first discussing with the trial doctor
- Record your disease symptoms every day in an electronic diary app (this will be provided)
- Collect stool samples as directed by the trial team, and prepare for certain visits that may require endoscopies
- Use appropriate contraceptive (birth control) methods throughout the trial, as directed by your trial doctor (if applicable)
- Please attend all study visits and immediately report any side effects or health problems you are having, even if you don't think they are important or related to the study procedures

[redacted]

[redacted]

[redacted]

## YOUR NEXT STEPS

If you decide to sign the patient information and consent form and join the [redacted] Clinical Trial, you will be provided with resources and information about what to do next.

If you would like to leave the trial for any reason at any point after enrollment, you may do so.

## THANK YOU

Thank you for considering the [redacted] Clinical Trial. We understand that decisions about your health are not always made easily. Participation in a clinical trial is a big undertaking, and we are grateful for your time and commitment. Without volunteers like you, medical advancements would not be possible.

**This patient information guide does not replace the need to ensure that participants understand all of the information provided in the patient information and consent form. You will be given time to think about what taking part in the trial will mean for you and to ask any questions. The trial team is here to support you.**