The University of Texas Medical Branch at Galveston
Minimal Risk Consent Form

Protocol Title: The Lived Experience of Patients with Chronic Gastrointestinal Disorders

IRB Number:

Principal Investigator: Kelsey Kent, 115 Carriage Court, Brentwood, TN, 37027; 423-506-9193

Why am I being asked to take part in this research study?

You are being asked to take part in this study because you have identified yourself as living with a chronic gastrointestinal disorder that has been diagnosed by your healthcare provider.

What is the purpose of this research study?

The purpose of this study is to explore what it is like to live with a chronic gastrointestinal disorder and reveal methods that participants use to manage their condition.

How many people will take part in this study?

About 25 people will take part in this study.

What procedures are involved as part of this research study?

If you agree to take part, you will be asked to sign this consent form and complete the following procedures. You will be asked to complete a short demographic form and to participate in up to two interviews with the principal investigator, either by phone or in person, each of which will last no longer than 90 minutes. These interviews will be audiotaped and transcribed, and you will be given the opportunity to review the transcripts for accuracy. Direct quotes may be taken from the transcript to use in reports of the study, but your name and personal information will be kept confidential. All materials, including audiotapes, transcripts, and forms will be assigned an individual identification number so that your name and personal information cannot be directly linked to the materials. All materials will be kept in a locked safe.

What are the possible risks for choosing to participate in this research study?

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. There is also a risk of emotional distress during interviews.

What are the potential benefits for participating in this research study?

You will not directly benefit from your participation in this research project. By explaining the lived experience of having a chronic gastrointestinal disorder, this study will benefit society in that it will identify the patient's perspective and provide information to enhance future research and treatment.

Will I be reimbursed for participating in this research study?

There will be no reimbursement for participation in this study. A gift card valued at $10 will be provided as a token of appreciation for your participation in the study.

Is there an alternative treatment/procedure?
The alternative is not to participate in the study.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if

- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.
- The researchers believe that participation in the research is no longer safe for you.

How will my information be protected?
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group. Although your direct statements may be quoted in the report, your name or other personal identifiable information will not be included in the report.

How will my privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study

number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Who can I contact with questions about this research study?
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Kelsey Kent, MSN, PMHNP at 423-506-9193 or, if after normal office hours, at kgkent@utmb.edu

This study has been approved by the UTMB Institutional Review Board (IRB). If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the IRB Office, at (409) 266-9475 or irb@utmb.edu.

Do I have to participate?
Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

Signature of Subject	Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject.

Signature of Person Obtaining Consent	Date and Time of Consent Obtained

Printed Name of Person Obtaining Consent