

# PARTICIPANT INFORMATION SHEET

<b>Title:</b>	<b>Body Surface Gastric Mapping to Evaluate Patients with Upper Gastrointestinal Symptoms and Controls</b>
<b>Lay Title:</b>	Non-Invasive Measurement of Gastric Motility
<b>Locality:</b>	Auckland District Health Board
<b>Lead Investigator:</b>	Associate Professor Gregory O'Grady, Phone: 09 923 9820 Department of Surgery, The University of Auckland, Auckland Clinical Campus, Level 12, Room 12087, Auckland City Hospital Support Building, Park Road, Grafton
<b>Head of Department:</b>	Professor Richard Douglas, Phone: 09 923 1658 Email: richard.douglas@auckland.ac.nz
<b>Study Personnel:</b>	Dr. Armen Gharibans, Dr. Elizabeth Broadbent, Dr. Peng Du, Dr. Celia Keane, Stefan Calder, Thomas Hayes, Daniel Carson, Nikita Karulkar
<b>Contact person:</b>	Dr. Armen Gharibans, Phone: 09 923 6528 Email: armen.gharibans@auckland.ac.nz

You are invited to take part in a non-invasive study to measure your stomach electrical activity (an ECG for the gut). Participation is **entirely voluntary (your choice)**. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the study Consent Form. You will be given a copy of the Participant Information Sheet to keep.

## WHAT IS THE PURPOSE OF THE STUDY?

About 30% of the adult population has some type of gastrointestinal (GI) disorder. Issues with the GI system not only affect digestion, but also impact the functioning of the brain and immune system. Functional GI disorders are poorly understood, highly prevalent and place a significant burden on the health care system, and the individual. The purpose of this study is to help develop a system for non-invasively monitoring and assessing the state of the GI tract (stomach and gut).

The electrical activity of the digestive system is complex and not well understood. Our study may help to gain new insight into the electrical activity of the GI tract and how this impacts its function.

We have designed a device that allows us to non-invasively record electrical activity of the GI tract similar to how the ECG records the activity of the heart. This recorded data can provide us with a wide range of information of the functioning of the digestive system.

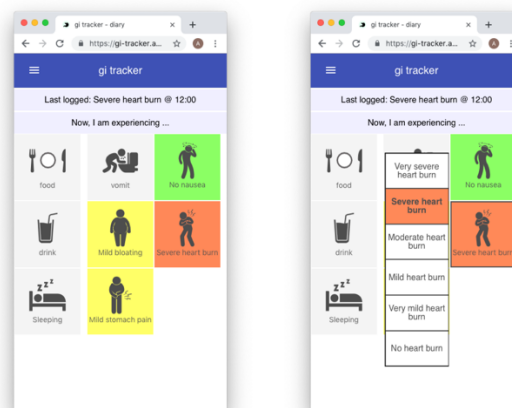
We want to perform the test on a large group of patients and healthy controls to understand whether it can reliably help doctors diagnose GI problems. We will aim to recruit up to 150 patients with active gastrointestinal symptoms along with 100 healthy controls in Auckland.

## WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you agree to take part in this study, we will ask you to join us for one of our non-invasive “ECG for the gut” tests.

The following would take place:

- 1) You will be contacted by a study investigator to schedule a time and location for your test. You will be asked to fast (not eat) prior to your test overnight (for at least 8 hours).
- 2) Upon arrival, you will be asked to fill out a symptom questionnaire a GI-related quality of life survey. The purpose of the questionnaire is to assess any gastrointestinal problems you have had in the previous two weeks. These questionnaires will take about 5 minutes to complete.
- 3) You will also be asked to fill out questionnaires to assess anxiety, depression, and adverse childhood experiences, since those have been found to be related to some GI problems. These are optional if you prefer not to complete them. Although the psychological questionnaires are not diagnostic, should their completion indicate the possibility of illness, this information will be sent to you. These questionnaires will take about 5 minutes to complete.
- 4) You will need to show your abdomen for the test. Women are not required to remove the clothing on their chest.
- 5) Excess abdominal hair may be removed to help electrode adhesion and your skin will be cleaned.
- 6) We may perform an ultrasound to confirm your stomach location.
- 7) A sensor array (up to 28cm x 17cm patch) will be applied to the skin overlaying your stomach and we will start recording your stomach activity.
- 8) You will be given a smartphone or tablet and be instructed on how to log symptom information throughout the study, using an App that looks like this:



- 9) After recording around 30 minutes of baseline activity, you will be asked to complete a 400 – 500 kCal meal (either a nutrient drink, energy bar, or sandwich).

- 10) We will continue to record for between 60 – 240 minutes. During this time you will be asked to keep quiet, but you will be freely able to go to the bathroom or stretch your legs, and are welcome to read something you bring with you.
- 11) After stopping the recording, the sensor array will be removed and disposed.
- 12) Your total involvement for this study will be between 2 to 5 hours.
- 13) You will be asked to fill out a feedback form at the end of the recording, including about whether the App was easy to use and accurately captured your symptoms.

You will be given the option to participate in a repeat study after 6-12 months.

We will collect some of your health information and demographics such as age, height, weight, gender and previous medical history. We may also access any previous abdominal CT scans (if you have had one) for anatomical information. An anonymous photograph (no face or identifying features) may be taken, if you allow it, to confirm placement of the electrode array. We may access your medical records to confirm the diagnosis of a GI disorder to allow validation of our device. This may include contacting your GP.

This research is part of a large international study for investigating gut problems using the new technology. Eventually, we hope to build up a database of up to 1000 patients, so that we can explore the links between abnormal gut electrical activity and symptoms very thoroughly. Your data may be included in this database, but the data will be completely de-identified before being included (meaning your personal details will be deleted).

## WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

As this study is aimed at developing and validating a new tool for measuring the electrical activity of the digestive system, there are no direct benefits to the participants in the study. However, this study may largely benefit the wider society in future as a tool for non-invasively monitoring and assessing GI function.

The recording devices have no known risks to your safety, however, wearing the device may cause some discomfort, but we will help you adjust the device so that you are comfortable throughout the recording process. Minor skin sensitivity could result from the skin prep used to help adhere the electrodes, or from wearing the electrodes themselves. Skin sensitivity/contact dermatitis has occasionally been reported as a result of wearing conventional electrodes. The skin prep and electrodes are similar to those used clinically for procedures such as ECG for many years and are generally well-tolerated.

## WHO PAYS FOR THE STUDY AND ARE THERE COMMERCIAL OUTCOMES?

This study is funded by a New Zealand Health Research Council (HRC) Programme Grant. The data will be owned by the University of Auckland. If the technology is successful, the new technology being developed at the University may also be commercialized in future. This could result in a product that can provide improved diagnosis for unexplained gut problems.

## WHAT IF SOMETHING GOES WRONG?

In the highly unlikely situation you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to

lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover. If you have any questions about ACC, contact your nearest ACC office or a study investigator.

## WHAT ARE MY RIGHTS?

Participation in this study is **entirely voluntary**, you are free to decline to participate, or withdraw from the research at any given time, without providing a reason, and this will in no way impact the care you receive. You also have the right to withdraw any information collected from you during the study, although data withdrawal is limited for up to 1 month after you have completed the recording and questionnaires.

You have the right to access any information that is collected about you during your enrolment in this study. The information that is gathered from you during your participation in the study will be kept confidentially and will be de-identified to ensure your privacy. No material which could personally identify you will be used in any reports on this study. We are happy to provide you with the results of your test if you are interested. It will be noted on the report that this is a research study and the results should not be used to inform clinical diagnosis or treatment. We are also happy to send you a lay summary of the overall results of this study upon its completion. Please note it may take time to collect data and provide results for this study.

## WHAT HAPPENS AFTER THE STUDY?

Your data will be de-identified following collection. This means your data will be assigned a unique code number. This code will not contain any personally identifying information. A separate document will be kept linking these codes to participants' names/NHI identifier. Only the researchers will have access to this document which will be kept under password security.

The research team will store a copy of the data on computer hardware at the University of Auckland. The Principal Investigator will be responsible for the safe keeping of the data. The data will be kept for 15 years following publication and then destroyed.

Members of the research team (present and future) will have access to the raw data and/or your clinical records during the study, but only where ethical approval has been attained. Future studies may wish to include this data. Where such use goes beyond that outlined in the present application, further ethical approval will be sought.

## WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Principal Investigator	Study Investigator/Contact Person
<b>Associate Professor Gregory O'Grady</b> greg.ogrady@auckland.ac.nz 09 923 9820	<b>Dr. Armen Gharibans</b> armen.gharibans@auckland.ac.nz 09 923 6528
<b>Postal Address:</b> Department of Surgery, The University of Auckland, Auckland Clinical Campus, Level 12, Room 12087, Auckland City Hospital Support Building, Park Road, Grafton	

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) at Auckland City Hospital by telephoning 09 486 8324 ext. 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by telephoning 09 486 8920 ext. 3204.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at [ahrec@auckland.ac.nz](mailto:ahrec@auckland.ac.nz) or at 373 7599 x 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

**Thank you for making the time to read about and consider taking part in this study.**

Approved by the Auckland Health Research Ethics Committee on 20/12/2019 for three years. Reference number [AH1130].