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Participant Information Sheet/Consent Form

Study Title	The use of point of care ultrasound (POCUS) to predict post operative ileus
Short Title	(GUILE) Gastrointestinal Ultrasound Ileus Study
Protocol Number	Version 1.2 16/3/2021
Project Sponsor	St. Vincent's Hospital, Melbourne
Coordinating Principal Investigator	Dr Tuong Phan
Associate Investigator(s)	Dr Louisa-Rose Bahnabhai, Dr Craig Delavari, Dr Ankur Sidhu, Dr Thomas Tiang, Mr Basil D' Souza, Dr Ian Richardson, Ms Katrina Hall, Dr Raymond Hu.
Location	St. Vincent's Hospital Melbourne, The Austin Hospital, Peter MacCallum Cancer Centre.

Part 1 What does my participation involve?

1 Introduction

We are inviting you to take part in a research project, which we hope will improve the care of patients who have surgery. This is because you are having routine surgery of the bowel. The research project involves using ultrasound to image your stomach and gastrointestinal tract to help us predict a post-operative complication known as 'ileus' or lack of movement of the bowel.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

2.1 Background information

The objective of this study is to identify whether the use of ultrasound imaging is helpful in predicting patients that develop post-operative bowel complications. Well established, studies suggest, the estimated incidence of post-operative bowel complications such as lack of bowel movement is approximately 8.5-10%. To date, the diagnosis of post surgical bowel complications is based on a wide range of variable clinical symptoms and observations by the treating clinician.

The use of ultrasound has been well established in assessing stomach volumes and the rate at which the stomach empties. Currently, there is no standardised pre or post surgical imaging technique to help clinicians predict the complication of 'lack of bowel movement'. This study will attempt to help identify ultrasound as a predictive screening tool, which could potentially be used to help improve clinical practice.
This research has been initiated by the study doctor: Dr Tuong Phan.

2.2. Trial sites and investigators

This study will be undertaken at three hospitals in Melbourne, St Vincent's Hospital Melbourne, the Austin and Peter MacCallum Cancer Centre. Additional centres in Australia and New Zealand may also be invited to participate at a later date. The study has been initiated and will be coordinated by Dr Tuong Phan, a Staff Specialist Anaesthetist at St Vincent's. Other researchers include surgical staff from the department of Colorectal Surgery and medical staff from Gastroenterology.

The study will recruit 90 participants over 12 months.

The study is funded by St Vincent's Health Australia. We do not receive sponsorship from external bodies or commercial entities.

3 What does participation in this research involve?

Participating in this study will involve you having an ultrasound of your gastrointestinal tract before and after your operation. Three scans will be performed in total before your surgery, and on the first and second days after your surgery is completed. This will be performed by an experienced doctor from our research team. Your surgery will proceed as planned and all of your treatment will not change.

Your experience and standard of care will be the same regardless of the ultrasound being performed, as any other patient presenting for routine bowel surgery.

Before Surgery

Before any study assessments are performed, you will be given a participant information and consent form (PICF) to read and sign in Pre- admission Clinic or the day before surgery.

Day of Surgery

Your details and consent will be confirmed by a member of the research team. Once you are changed into your patient gown and lying on a bed in preparation for surgery, you will be taken to the anaesthetic room. Standard continuous monitoring of your heart rhythm, oxygen levels and blood pressure are typically started in the anaesthetic room.

Then trained member of the research team will perform the gastrointestinal ultrasound. Gel is applied to your skin over the area being examined. This water-based gel is easy to remove from skin and, if needed, clothing. The researcher will press a small, hand-held device (transducer) against the area being studied and moves it as needed to capture the images. The transducer sends sound waves into your body, collects the ones that bounce back and sends them to a computer, which creates the images. This should take 5-10 minutes.

After surgery

A bedside ultrasound will be performed on your first and second days after your surgery as previously described, by a member of our research team. A morning scan will be performed prior to breakfast. This involves a scan on an empty stomach and then drinking 250mls of water. 2 further scans will be performed up to 60mins after drinking the water. You can then resume eating and drinking as guided by the surgical team.

A single subsequent scan will also be performed later in the afternoon, but this will not require you to be fasted.

Scans may be undertaken on day 3 and subsequent days if you are still not eating and drinking.

All gastrointestinal imaging will be saved. Measurements from these images will be used help in the assessment to predict post surgical complications.

There are no costs associated with participating in this research study, nor will you be paid. Once the study is completed, analyses of the collected information will be performed and results presented in relevant peer-reviewed biomedical conferences and journals.

4 What do I have to do?

Participation in this study is entirely voluntary. There will be no alterations to your surgery or recovery. If you do decide to take part, you will be given this participation information and consent form to keep. You will be seen regularly during your admission by the research staff and asked questions. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with St Vincent's Hospital Melbourne.

5 Other relevant information about the research project

In total there will be about 90 participants taking part in the study. They will all be recruited from the participating hospitals.

6 Do I have to take part in this research project?

No. It is up to you to decide whether or not to take part in the study. If you decide to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. If you decide not to take part, or later to withdraw, this will not affect the standard of care you receive.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. As previously mentioned your standard of care or treatment will not change. Your study doctor will be available to answer any questions you might have before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

You will receive additional visits after your surgery, which may allow us to detect any problems at an earlier stage, but we cannot guarantee or promise that you will receive any benefits from participation in this project.
Knowledge gained from this research may assist us in treating other patients in the future.

9 What are the possible risks and disadvantages of taking part?

Ultrasound is a safe and non-invasive diagnostic technique to image inside the body. It is a safe procedure that uses low-power sound waves. There are no known risks.

A trained member of the research team will press a small, hand-held device (transducer) against the area being studied and moves it as needed to capture the images.

Ultrasound is usually painless. However, you may experience mild discomfort as we guide the transducer over your body. The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features. This study does not involve radiation exposure

Participation can be discontinued at any time and information on data storage and disposal will be given to participants.

10 What will happen to my test samples?

You will be required to have routine blood / urine tests around the time of your surgery as per routine care. We will collect information from these routine tests as part of this study. An additional blood collection, 5-10mls, may be used check for markers of inflammation. These will be taken at the same time of routine blood collection where possible. No other blood or tissue samples will be taken from you for the purpose of this study.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If

you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13 What if I withdraw from this research project?

You can opt out of the study at any time before or after the surgery. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you and we will not contact you or review your medical notes any further. In this case we would like to keep the information we collected about you up to the point of leaving the study, unless you specifically request that we do not do this.

14 Could this research project be stopped unexpectedly?

It is unlikely that we will need to stop the project unexpectedly.

15 What happens when the research project ends?

We plan to make available a report of our results at the end of this study, which we can provide to you on request.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

All information about you in connection to this study will be collected in non-identifiable form and remain strictly confidential. It will be disclosed only with your permission by signing the attached consent form, or except, as required by law. Your health care records will be seen by authorised members of the research team at the hospital so that they can collect information needed for this study.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

In accordance with Victoria's privacy law's, you have the right to request access to the information about you that is collected and stored by the research team. Participants may request access to their own data and correct any information if necessary.

It is anticipated that the results of this research study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. A summary of results of the study will be provided to you upon request.

It may be that during the course of the study the researchers will uncover further questions that can be answered using the data you provide. If that is the case, study data may be used for other research publications. Your data will not be shared in any form with any third party during the course of this further research, nor will you need to be contacted to assist further.

It is possible that the data collected about you during this study may be used by the same research group in the future to answer related research questions. You will not be contacted again to obtain more data in the event that such a study is planned, and your data will not be shared with any third party.

17 Complaints and further information

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you want any further information concerning this project or if you have any concerns which may be related to your involvement in the project, you can contact Dr Tuong Phan at *tuong.phan@svha.org.au*.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the Executive Officer, St Vincent's Hospital Melbourne Human Research Ethics Committee (below):

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	St Vincent's Hospital Melbourne HREC
Position	HREC Executive Officer
Telephone	(03) 9231 2394
Email	research.ethics@svhm.org.au

Local HREC Office contact

Name	St Vincent's Hospital Melbourne Human Research Ethics Committee
Position	HREC Executive Officer
Telephone	(03) 9231 2394
Email	research.ethics@svhm.org.au

18 Who is organising and funding the research?

This research project is being conducted by Dr Tuong Phan together with clinicians from the Department of Anaesthesia and Colorectal Surgery.

You will not benefit financially from your involvement in this study even if, for example, knowledge acquired from your information proves to be of commercial value to St Vincent's Hospital Melbourne. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

The ethical aspects of this research project have been approved by an independent group of people a Human Research Ethics Committee of St Vincent's Hospital, Melbourne. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007).

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor on **0392314253** or any of the following people:

Clinical contact person

Name	Dr Tuong Phan
Position	Principal Investigator
Telephone	0392314253
Email	tuong.phan@svha.org.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	
Position	Patient liaison officer
Telephone	*92313108*
Email	

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	St. Vincent's Hospital Melbourne HREC
HREC Executive Officer	Executive Officer of Research
Telephone	92312394
Email	Research.ethics@svhm.org.au

Local HREC Office contact (Single Site - Research Governance Officer)

Name	Executive Officer of Research
Position	Executive Officer of Research
Telephone	92313930
Email	Research.ethics@svhm.org.au

Consent Form - *Adult providing own consent*

Title	The use of point of care ultrasound (POCUS) to help predict post operative Ileus
Short Title	(GUILE) Gastrointestinal ultrasound ileus study
Protocol Number	1.2 16th March 2021
Project Sponsor	St. Vincent's Hospital Melbourne
Coordinating Principal Investigator/ Principal Investigator	Dr. Tuong Phan
Associate Investigator(s)	Dr Louisa-Rose Bahnabhai, Dr Craig Delavari, Dr Ankur Sidhu, Dr Thomas Tiang, Mr Basil D' Souza, Dr Ian Richardson, Ms Katrina Hall, Dr Raymond Hu
Location	St. Vincent's Hospital Melbourne, The Austin Hospital, Peter MacCallum Cancer Centre.

Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

❒ Consent was obtained via telephone / telehealth with _____
(name of Participant) on _____ (date).

Form for Withdrawal of Participation - *Adult providing own consent*

Title	The use of point of care ultrasound (POCUS) to predict post operative Ileus
Short Title	(GUILE) Gastrointestinal Ultrasound Ileus Study
Protocol Number	1.0 1st November 2020
Project Sponsor	St. Vincent's Hospital Melbourne
Coordinating Principal Investigator/ Principal Investigator	Dr Tuong Phan
Associate Investigator(s)	Dr Louisa-Rose Bahnabhai, Dr Craig Delavari, Dr Ankur Sidhu, Dr Thomas Tiang, Mr Basil D' Souza, Dr Ian Richardson, Ms Katrina Hall, Dr Raymond Hu
Location	St. Vincent's Hospital Melbourne, The Austin Hospital, Peter MacCallum Cancer Centre.

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with St. Vincent's Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.