MAIN PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Study Title: A randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer

Principal Investigator: Professor Trevor Leong

Study Sponsor: Australasian Gastro-Intestinal Trials Group (AGITG)

This Participant Information and Consent Form is 14 pages long. Please make sure that you have all the pages.

You are being asked to take part in a research study.

This Participant Information contains detailed information about the research study. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in the study before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the study with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the study is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent form to keep as a record.

1. What is the purpose of this study?

Your doctor has explained to you that the main treatment for your stomach cancer is surgery. However, even with good surgery there is still a risk that the cancer may come back if no further treatment is given. Over the last 5 years, 2 large international studies have shown that giving additional treatment with radiotherapy and chemotherapy may improve the chances of curing patients with stomach cancer. Firstly, a large British study called “MAGIC” has shown that giving chemotherapy BEFORE and AFTER surgery is better than just surgery alone (some recent studies have also shown that there are several different types of chemotherapy that can be used in this treatment). Secondly, a large US study called “INT0116” has shown that giving combined chemotherapy and radiotherapy together (chemoradiation) AFTER surgery is better than surgery alone. These 2 studies have caused some confusion amongst doctors because we do not know which treatment is better. In other words, is combined chemotherapy plus radiotherapy more effective than chemotherapy alone in improving the cure rates for stomach cancer?

The purpose of this study is to compare these 2 treatments to determine which is better. Unlike in the US study, in this study we will be giving chemoradiation
BEFORE surgery (preoperative treatment), rather than AFTER surgery (postoperative treatment). This is because we know from studies in other types of cancers that preoperative treatment is better than postoperative treatment. In addition, preoperative treatment also produces fewer side effects so that patients are more likely to complete the planned treatment. The main aim of this study is therefore to determine if preoperative chemoradiation is more effective than preoperative chemotherapy alone for patients with localised stomach cancer who are going to be treated with surgery. We will also be looking at the side effects of the two treatment combinations.

This study is being conducted in Australia, New Zealand and Singapore by the Australasian Gastro-Intestinal Trials Group (AGITG) and the Trans-Tasman Radiation Oncology Group (TROG). It is also likely that other countries will join the study. The trial would aim to recruit 620 patients over 10 years, and patients would be monitored for a further three years once the recruitment target is reached.

2. Why have I been asked to participate in this study?

You have been selected to participate in this study because you have been diagnosed with cancer of the stomach. Your doctor believes that your cancer may be suitable for removal by surgery, and that you may benefit from additional treatment with chemotherapy or chemoradiation. As described above, previous studies have shown that various combinations of chemotherapy and radiotherapy given either before or after surgery may reduce the likelihood of the cancer returning after surgery, and therefore improve the likelihood of cure. This study will compare different treatment combinations to determine which is better in curing the cancer.

Some of the treatments being investigated in this study differ from the standard treatment offered in this institution because they involve the use of chemoradiation before surgery, rather than after surgery. However, we believe that this is a much better way of giving chemoradiation because it is associated with fewer side effects and may be more effective in treating the cancer. The alternatives to participation in this study include surgery without any chemotherapy or radiation, or surgery plus one of the two treatments that are being compared in this study; that is, additional chemotherapy alone, or additional chemoradiation. Your doctor can discuss the alternatives with you. You may ask the investigator for information about your disease and the benefits and risks of the treatments available. You may choose one or more of these treatments rather than participate in this study.

3. What if I don't want to take part in this study, or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you wish to participate. Your choice not to participate will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

Before you make your decision, the Investigator or a member of the study team will be available so you can ask any questions you have about the study. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may impact on your willingness to continue in the study.
If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

If you decide to withdraw from this study, please notify a member of the research team before you withdraw. This notice will allow your doctor to inform you if there are any health risks or special requirements linked to withdrawing.

If you decide to discontinue the study treatment, you will be asked to attend follow-up visits to allow collection of information regarding your health status. Alternatively, the investigator/sponsor will request your permission to access your medical records for collection of follow-up information for research and analysis.

In the event that you withdraw your consent, the effective date of the notification will be the date on which your withdrawal is received by the AGITG Gastric Study, and that information about you collected prior to that date will continue to be used and form part of this project.

Your study doctor may withdraw you from the study if he/she does not think it is in your best interests to continue or if you are unable to complete the study procedures.

4. What does this study involve?

If you join the study, you will be expected to attend the following visits over a period of approximately 28 weeks:

- 1 set of screening visits over a period of 3 weeks
- Up to 20 chemotherapy visits (once a week during chemotherapy)
- 25 radiotherapy visits if being treated with chemoradiation (daily, Monday to Friday, for 5 weeks)
- 1 set of pre-surgery visits over a period of 3 weeks
- 1 surgery

Following treatment, you will be expected to attend approximately 14 follow-up visits over a period of 5 years (one visit every 3-6 months).

You will be asked to fill in Quality of Life questionnaires before you start treatment, twice during preoperative treatment, before surgery, around 1, 4, 6, 9 and 12 months after surgery and at each subsequent follow-up appointment until 5 years. This is so we can find out how you are feeling in yourself and the effect treatment has upon you and your daily activities.

It is important to tell your doctor and the study staff about any treatments or medications you may be taking, including non-prescription medicines, vitamins or herbal remedies and any changes to these during the study.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

Initially you will be assessed to check that you are suitable to join the study. This screening period may last for up to 3 weeks and will involve the following procedures. All of the tests that you will undergo during this study would normally be done as part of your standard care, even if you were not participating in this study.

- History and physical examination including height and weight
- Assessment of nutritional status
- ECG
- Blood tests for blood counts, liver and kidney function
- A kidney scan called a “renal scan” to look at the function of both kidneys
- An endoscopy and biopsy
CT scan chest, abdomen and pelvis
- Laparoscopy (only for some patients)
- An endoscopic ultrasound (only for some patients)
- A PET scan (Positron Emission Tomography) if available

If you are suitable, you will be randomised into one of the study groups described below. Randomisation means that you are put into a group by chance, like the toss of a coin. A computer program will choose which group you are allocated to. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group. You will be told which treatment you will receive.

The study design would have patients split randomly into 2 treatment groups:

**Group 1:**
3 cycles of chemotherapy consisting of either: epirubicin, cisplatin, 5-fluorouracil [ECF]; epirubicin, cisplatin, capecitabine (Xeloda) [ECX]; epirubicin, oxaliplatin, capecitabine (Xeloda) [EOX], OR 4 cycles of FLOT (fluorouracil, leucovorin, oxaliplatin, docetaxel) followed by
- surgery, followed by
- 3 cycles of chemotherapy consisting of either: epirubicin, cisplatin, 5-fluorouracil [ECF]; epirubicin, cisplatin, capecitabine (Xeloda) [ECX]; epirubicin, oxaliplatin, capecitabine (Xeloda) [EOX] OR 4 cycles of FLOT (fluorouracil, leucovorin, oxaliplatin, docetaxel)

**Group 2:**
- 2 cycles of chemotherapy consisting or either: epirubicin, cisplatin, 5-fluorouracil [ECF]; epirubicin, cisplatin, capecitabine (Xeloda) [ECX]; epirubicin, oxaliplatin, capecitabine (Xeloda) [EOX] OR 3 cycles of FLOT (fluorouracil, leucovorin, oxaliplatin, docetaxel) followed by
- chemoradiation (radiotherapy plus 5-fluorouracil (or capecitabine) chemotherapy), followed by
- surgery, followed by
- 3 cycles of chemotherapy consisting of either: epirubicin, cisplatin, 5-fluorouracil [ECF]; epirubicin, cisplatin, capecitabine (Xeloda) [ECX]; epirubicin, oxaliplatin, capecitabine (Xeloda) [EOX] OR 4 cycles of FLOT (fluorouracil, leucovorin, oxaliplatin, docetaxel)

There are several different accepted chemotherapy regimens that can be used for stomach cancer. Your doctor will determine which chemotherapy regimen is most suitable for you.

If you take part in this study you will receive the following treatments:

**Stage 1: Preoperative treatment (treatment before surgery)**
If you are randomised into group 1, you will receive chemotherapy given either as:
- 3 treatment ‘cycles’ of 3 weeks each, totalling 9 weeks. Each cycle consists of 3 separate drugs called epirubicin, cisplatin, and 5-fluorouracil [ECF], or epirubicin, cisplatin and capecitabine (Xeloda) [ECX]), or epirubicin, oxaliplatin and capecitabine (Xeloda) [EOX].

or
- 4 treatment ‘cycles’ of 2 weeks each, totalling 8 weeks of fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT).
On the first day of each cycle, for ECF, you will receive epirubicin through a drip into your vein (intravenously) over approximately 1 hour. After this, you will then receive cisplatin intravenously over approximately 1 hour. Once the cisplatin has been given you will then receive intravenous 5-fluorouracil continuously for the next 21 days, using a pump which you carry around with you (see below). If you receive ECX chemotherapy, the epirubicin and cisplatin are given as above and the capecitabine is taken as tablets, twice a day. If you receive EOX you will receive epirubicin and oxaliplatin through a drip and the capecitabine is taken as tablets, twice a day. Because you need to be well hydrated before and after receiving the cisplatin, you may need to be admitted to hospital overnight for intravenous fluids. Apart from this possible one night admission to hospital, the remainder of your chemotherapy treatment is usually given as an outpatient. If you receive FLOT you will receive docetaxel, oxaliplatin and leucovorin on day 1 through a drip and then you will receive intravenous 5-fluorouracil continuously over 24 hours, using a pump.

If you are randomised into group 2, you will receive the same ECF or ECX or EOX or FLOT chemotherapy, but one cycle less than patients in group 1 (ie. 2 cycles of ECF / ECX / EOX or 3 cycles of FLOT). Two weeks after completing the chemotherapy, you will start chemoradiation. This will consist of radiotherapy which is given once a day, five days a week, Monday through Friday, for 5 weeks. During your radiation, you will also receive 5-fluorouracil (or capecitabine). The 5-fluorouracil will be given continuously through a tube in your vein, 7 days a week, for the full 5 weeks of radiation. If you receive capecitabine instead of 5-fluorouracil, you will take the capecitabine tablets twice a day throughout the period of radiotherapy.

In order to deliver the continuous infusion of 5-fluorouracil, you will carry around a small battery-operated pump (a little bigger than a portable CD player), which slowly pumps the 5-fluorouracil chemotherapy into a vein. In order to pump the chemotherapy into the vein, an access device known as an “infusaport” or “PICC line” will need to be put into a vein, and this can stay in place for many months if necessary. An infusaport is a drip placed under the skin, which passes into a blood vessel in the chest. The infusaport lies underneath the skin and cannot be seen, but it can be felt. Alternatively, a Peripherally Inserted Central Catheter (PICC line) may be used where the drip is inserted in the crease of your arm. It is placed in your vein and will pass up your arm and into your chest. The other end of the catheter will rest on the outside of your arm. Insertion of an access device takes about an hour and is performed in the hospital.

Stage 2: Surgery

You will undergo surgery approximately 4-6 weeks after finishing the preoperative treatment. Before surgery, a number of tests will be done to check that you are fit enough to undergo surgery, and that your cancer is still suitable for surgery. If your cancer has gotten worse during the treatment, there is a chance that surgery may not be possible, and your doctor can discuss alternative treatment options with you at that time.

The tests will be similar to those performed before the treatment started, as follows:

- History and physical examination including height and weight
- Assessment of nutritional status
- ECG
- Blood tests for blood counts, liver and kidney function
- CT scan chest, abdomen and pelvis

The study pathologist, located at Peter MacCallum Cancer Centre, may review the tissue removed during your surgery to evaluate the tumour. This is done to determine if there are any differences between the information provided by the hospital
pathologist and the evaluation of the study pathologist. This is one of the quality assurance measures of the study. Approximately 1 in 10 participants will be selected to have their tissue reviewed, we will not know in advance if this is the case for you. If your tissue is selected for review the samples will be sent to the pathologist at Peter MacCallum Cancer Centre. Once the review is complete the tissue will be returned to the hospital laboratory where you had your surgery.

By consenting to participate in this study, you consent to the various blood and other tests for the purposes noted above.

Stage 3: Postoperative treatment (treatment after surgery)

Patients in both groups 1 and 2 will receive a further 3 cycles of ECF (or ECX) or EOX) or chemotherapy, which will take 9 weeks to deliver or 4 cycles of FLOT which will take 8 weeks to deliver. This chemotherapy is exactly the same as the chemotherapy that is given in stage 1 before surgery. The first cycle of chemotherapy will begin 4 to 10 weeks after surgery depending on how you are recovering from the effects of surgery.

While receiving the study treatment you will be reviewed regularly by your doctor. During chemotherapy you will be seen regularly by the medical oncologist to assess any side effects of treatment and to monitor your nutritional status and weight. You will also have regular blood tests to monitor your blood counts, as well as kidney and liver function. While you are receiving radiotherapy, you will be seen weekly by the radiation oncologist to assess any side effects of treatment. Your doctor may prescribe medication to keep these side effects under control. Most of the side effects from chemotherapy and radiotherapy should subside 3 to 4 weeks after completing treatment. However, symptoms of tiredness and fatigue may persist for several months and your weight may take several months to return to normal.

Follow up

After you have finished the treatment, you will be followed up every 3-6 months by your doctor to check your health and get some information on any therapy you may have received after the end of the study treatment - this is normal procedure and would occur regardless of whether you were on the trial or not. More scans may be done during follow-up as well, depending on your condition. If you withdraw from study treatment prematurely for any reason, we would still, with your permission, contact you to collect this information.

5. Are there risks to me in taking part in this study?

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study.

Possible risks, side effects and discomforts include:

Radiotherapy

Radiotherapy may cause reddening or tanning of the skin, hair loss in the treatment area, nausea, vomiting, loss of appetite, weight loss, and weakness. Kidney damage or liver damage may occur if the kidney or liver is in the same field of radiation.
Common: (1 in 10)
- Nausea and/or vomiting
- Weakness and fatigue
- Loss of appetite
- Weight loss
- Reddening or tanning of the skin
- Hair loss in the treatment area

Uncommon, but serious (less than 1 in 20):
- Kidney damage - decreasing the kidneys’ ability to handle the body’s waste which may be permanent
- Liver damage - decreasing the liver’s ability to handle the body’s waste which may be permanent
- Damage to the small bowel eg. causing bowel obstruction

Epirubicin chemotherapy
Common: 1 in 10
- Nausea and/or vomiting
- Mouth sores
- Hair loss which is temporary
- Decrease in blood counts which can lead to a risk of infection and bleeding

Rare, but serious: 1 in 100
- Damage to the muscles of the heart
- Damage to the veins where the drip is put in

Cisplatin chemotherapy
Common: 1 in 10
- Decrease in blood counts which can lead to a risk of infection and bleeding
- Loss of appetite and/or taste; metallic taste in your mouth
- Nausea and/or vomiting
- Fatigue
- Hearing loss or ringing in the ears
- Numbness or tingling in the hands or feet

Rare: 1 in 100
- Muscle cramps or spasm
- Loss of coordination (rare)
- Involuntary movements or shaking (rare)

Rare, but serious: 1 in 100
- Loss of muscle or nerve function which may cause weakness or numbness in your hands and feet
- Facial swelling
- Decreasing ability of the kidneys to handle the body’s waste and make urine which may be permanent
- Allergic reactions which can cause difficulty in breathing, fast heartbeat, and sweating
- Decrease in liver function
- Other cancers called acute leukemia
- Changes in the brain that can cause clumsiness, weakness, visual, speech, and sometimes cognitive changes, which may be reversible or permanent
5-fluorouracil (and 5-fluorouracil + Leucovorin) chemotherapy

Common: 1 in 10
- Decrease in blood counts which can lead to a risk of infection and bleeding
- Loss of appetite
- Nausea and/or vomiting
- Diarrhea with cramping or bleeding
- Skin rash
- Fatigue
- Headaches
- Hair loss which is temporary
- Mouth sores
- Sore throat

Rare: 1 in 100
- Darkening of the skin, nails, or veins
- Inflammation of the veins
- Confusion
- Inflammation of the fingers and toes
- Increased sensitivity to sunlight
- Loss of coordination or balance

Rare, but serious: 1 in 100
- Chest pain that may be associated with damage to the heart

Capecitabine (Xeloda) chemotherapy

Common: 1 in 10
- Decrease in blood counts which can lead to a risk of infection and bleeding
- Loss of appetite
- Nausea and/or vomiting
- Diarrhea with cramping or bleeding
- Skin rash
- Fatigue
- Headaches
- Hair loss which is temporary
- Mouth sores
- Sore throat
- Inflammation of the fingers and toes

Rare: 1 in 100
- Inflammation of the veins
- Confusion
- Increased sensitivity to sunlight
- Loss of coordination or balance
- Severe dehydration which may lead to kidney failure

Rare, but serious: 1 in 100
- Chest pain that may be associated with damage to the heart

Very rare:
Severe skin reactions such as Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis which may cause severe skin rash with blisters and peeling.

**Oxaliplatin chemotherapy**

**Common: 1 in 10**
- Decrease in blood counts which can lead to a risk of infection and bleeding
- Loss of appetite
- Nausea and/or vomiting
- Diarrhea with cramping or bleeding
- Skin rash
- Fatigue
- Headaches
- Hair loss which is temporary
- Mouth sores
- Sore throat
- Cough
- Bleeding nose
- Conjunctivitis
- Deep vein thrombosis (blood clot)
- Numbness or tingling in the hands or feet on cold exposure. This can become persistent.
- Sensation of tightness or fullness in the throat on drinking cold fluids

**Rare: 1 in 100**
- Allergic reactions which can cause difficulty in breathing, fast heartbeat, and sweating
- Damage to the veins where the drip is put in
- Blockage or swelling of the bowel

**Very rare:**
- Loss of hearing
- Reversible short-term vision loss
- Liver damage

**Docetaxel chemotherapy**

**Common: 1 in 10**
- Decrease in blood counts which can lead to a risk of infection and bleeding
- Loss of appetite
- Nausea and/or vomiting
- Diarrhea with cramping or bleeding
- Skin rash
- Fatigue
- Hair loss which is temporary
- Mouth sores
- Fluid retention
- Numbness and tingling in the hands or feet
- Allergic reaction
• Joint and muscle pains or cramps
• Nail changes

Rare: 1 in 100
• High blood pressure
• Redness, tenderness and thinning of skin on the palms of hands and soles of feet
• Abnormal liver enzymes on blood tests

Rare, but serious
• Irregular heartbeat or damage to the heart

**Combined ECF (or ECX) or EOX chemotherapy and chemoradiation**
Rare, but serious: 1 in 100
• Death resulting from complications of chemotherapy with or without radiotherapy

**The PICC line or Infusaport**
Common: 1 in 10
• Pain
• Infection
• Bruising
• Blood clot in the vein

**Surgery**

**Early Complications**
Common: 1 in 10
• Wound infection

Rare: 1 in 100
• Leakage from the join of the oesophagus and stomach
• Respiratory infection
• Postoperative bleeding
• Duodenal stump leak
• Deep infection
• Perioperative death
• Bile leakage
• Injury to bile duct

**Late Complications**
Common: 1 in 10
• Bowel obstruction
• Bile gastritis/reflux
• Ulceration at join

Rare: 1 in 100
• Nutritional deficiencies
• Dumping syndrome

There is a possibility that some of these surgical risks may be increased following radiotherapy and chemotherapy, but we will be carefully monitoring the progress of the trial to ensure patient safety.
Risks related to pregnancy

It is important that women participating in this study are not pregnant and do not become pregnant during the study as the study treatments may damage an unborn baby. The effect of the study treatments on an unborn baby is unknown. If you are a woman of childbearing age and there is any possibility that you are pregnant, your doctor will need to perform a urine pregnancy test before you start in the study. If necessary, you should use reliable contraception (such as oral or implanted contraceptive or an IUD) during the course of the study. If you think you may be pregnant, it is important to let your doctor know immediately.

Risks related to fertility

Chemotherapy and radiotherapy may cause temporary or permanent sterility. Please discuss this with your doctor if you have any concerns about future fertility.

6. What happens if I suffer injury or complications as a result of the study?

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment. Treatment for the injury or complication will be provided free-of-charge a public hospital.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

In the event of loss or injury, the parties involved in this study agree to be bound by the Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial of Medicines Australia. A copy of these guidelines is available from the Secretary of the Ethics Committee.

By signing the consent form, you have not waived any legal or other right to seek compensation.

7. Will I benefit from the study?

The study aims to further medical knowledge and may improve future treatment of stomach cancer. We hope that the treatment being investigated in this study will benefit some patients with stomach cancer, but we cannot guarantee that taking part in the study will be of direct benefit to you. We hope the information learned from this study will benefit other patients with stomach cancer in the future.

8. Will taking part in this study cost me anything?

There will be no additional costs to you for the study visits and procedures. You will be asked to pay for the cost of the drugs that would normally be prescribed for your
condition at prices determined by the Pharmaceutical Benefits Scheme (PBS). Please note however that not all drugs are included on the PBS for all patients (eg. capecitabine); your doctor will be able to explain the cost of the drugs prescribed to you. This would be the same as if you were not participating in this study. You will not be paid for participation in this study.

The cancer centre responsible for your treatment will receive some payment from the Australasian Gastro-Intestinal Trials Group to offset the costs of running the trial. No individual researcher will gain direct financial benefit from conducting this study.

9. How will my confidentiality be protected?

Nursing and medical staff involved in your care will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will not be disclosed without your permission, except as required by law.

Your health records and any information obtained during the study may be examined by authorised representatives of the hospital’s Health Research Ethics Committee, the study sponsor (the Australasian Gastro-Intestinal Trials Group), or by regulatory authorities such as the Australian Government’s Therapeutic Goods Administration (TGA) or as required by law, for the purposes of verifying the study procedures or data. By signing the Consent Form, you authorise access to this confidential information to the relevant study personnel and regulatory authorities as noted above.

10. What happens with the results?

Your doctor will inform you about your own results where relevant.

If you give us your permission by signing the Consent Form, we plan to discuss/publish the results of the study via peer-reviewed journals, presentations at conferences or other professional forums. In any publication, information will be provided in such a way that you cannot be identified.

Results of the study will be provided to you, if you wish, by your study doctor.

11. What happens to my treatment when the study is finished?

This decision will be made in consultation with you and your treating doctor about the most appropriate treatment for you at that time.

12. Further Information or Any Problems

If you require further information or if you have any problems concerning this study (for example, any side effects), you can contact the principal investigator or study staff. The investigators responsible for this study are [list the names and contact phone numbers, including after hours numbers].

Name: [Principal investigator or study team contact person]
Position:
Telephone:
13. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X17-0370 (previously X13-0174).

[If appropriate:] The conduct of this study at the [name of hospital] has been authorised by the [name of Local Health District]. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer [or other officer] on [telephone number] and quote protocol number [insert local protocol number].

Thank you for taking the time to consider being part of this study.
If you wish to take part in this study, please sign the attached consent form.
This information sheet is for you to keep.
MASTER PATIENT CONSENT FORM

I, ....................................................................................................................... [name]
Of. ....................................................................................................................... [address]
have read and understood the Information for Participants on the above named research study. I understand that I am agreeing to participate in a research study.

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or side effect, and of their implications as far as they are currently known by the researchers.

I understand that the research project will be carried out according to the principles in the National Health & Medical Research Council Statement on Ethical Conduct in Research Involving Humans.

I freely choose to participate in this study and understand that I can withdraw at any time.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

NAME: .........................................................
SIGNATURE: .........................................................
DATE: .........................................................

NAME OF WITNESS: .........................................................
SIGNATURE OF WITNESS: .........................................................
DATE: .........................................................

NAME OF INVESTIGATOR: .........................................................
SIGNATURE OF INVESTIGATOR: .........................................................
DATE: .........................................................