

**Clinical Trial Name:** Description of the clinical trial and its proposed outcomes.

The Hospital will place their logo and details here.

## **PARTICIPANT INFORMATION AND CONSENT FORM TEMPLATE**

**Clinical Trial Name:** Description of the clinical trial and its proposed outcomes.

**Principal Investigators:** Names of the doctor(s)

Please make sure you have all 10 pages of this document.

### **You are being invited 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 this 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 this study with a relative or friend or your local health worker.

Once you understand what this 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 study.

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?**

Colorectal cancer is a common disease that arises initially in the bowel and then may spread further to other parts of the body including the liver and lungs. One in four patients diagnosed with colorectal cancer have disease that has spread outside of the bowel. This stage of disease is often incurable. Therefore, the aim of treatment in this situation is to control any symptoms and prolong a person's life.

If the cancer is contained within the bowel, the usual treatment in this situation is surgery to remove the primary cancer. If the cancer has spread to other organs, it is not clear whether or not surgery should be undertaken. The advantage of early elective surgery is that it may prevent problems like bowel blockage or bleeding in the future. On the other hand, it does mean that patients have to undergo a major operation and the associated recovery process before they are able to commence any chemotherapy treatment for the bowel cancer which has spread. The advantage of proceeding with initial chemotherapy (without surgical removal of the primary tumour) is that there is no delay in starting treatment for the bowel cancer that has spread. We also know that the primary tumour

only causes problems like bowel blockage and bleeding in a minority of cases (approximately 1 in 5) so it could be argued that most people will never require an operation. On the otherhand, for those people who do end up with problems related to their primary tumour, it is likely that the risks associated with emergency surgery would be greater if they are already on chemotherapy treatment, especially if that treatment also includes one of the new antibody treatments bevacizumab (Avastin).

In routine practice, some patients have surgical removal of the primary tumour and others do not. There is no clear evidence of which is the best approach. This study is aiming to determine whether initial elective surgery or initial chemotherapy approach is better, by assessing the impact of both

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approaches on the rate of complications associated with the primary tumour, quality of life and survival.

### **The purpose of this “Clinical Trial Name”**

*Sample text:* The purpose of the study is to determine whether initial elective surgery to remove the main colon or rectal cancer tumour decreases intestinal complications such as obstruction (blockage of the intestines preventing the normal flow of the products of digestion), perforation (perforation or a breakdown of the wall of the stomach, small intestine or large bowel, resulting in intestinal contents flowing into the abdominal cavity), pain and bleeding.

This study will also compare whether patients with colon or rectal cancer benefit through improved quality of life and increased survival by undergoing surgery followed by chemotherapy/chemoradiotherapy compared with undergoing initial chemotherapy/radiotherapy without elective surgery.

### **Research results**

*Sample text:* The results of the study will enable us to make this comparison and will be of great benefit in determining the best way to manage patients with your cancer.

This study is being sponsored by the Australasian Gastro-Intestinal Trials Group (AGITG) and is being conducted by the NHMRC Clinical Trials Centre. The Principal Investigator at this hospital will be paid a *nominal* amount to cover the costs of your participation in the study. The sponsor and the investigator do not have a financial interest in the outcome of this study.

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

You are eligible to participate in this study because you have been diagnosed with advanced colorectal cancer that has spread to other parts of your body. Your doctor believes that your cancer is suitable for surgery, chemotherapy or chemoradiotherapy.

*Sample text:* The study aims to recruit 300 patients with advanced colorectal cancer in Australia and New Zealand.

## **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. The alternative to participating in this study is to have the standard treatment of care for colorectal cancer at this institution as per your treating doctor's recommendation.

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 surgical techniques, chemotherapy and radiotherapy may become available during the course of the study. You or your legally acceptable representative will be kept informed of any significant new findings that may affect 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 further participation, 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 withdraw from the study, you will be asked to attend follow-up visits to allow collection of information regarding your health status. If this is not possible, 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 SUPER study doctor at your hospital, and 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 approximately 6 study visits, one per month over a period of 6 months, including a period in hospital while having surgery if you are randomised to receive surgery. These visits will usually link in with your appointments for chemotherapy or radiotherapy, or with visits to your surgeon.

Information about how you are feeling will be collected every 3 months for a maximum of 2 years. This information may be collected during your visits to your doctor or the study staff may call you every 3 months to collect the information over the phone.

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.

Initially you will have been assessed by your doctor to check that you are suitable to join the study. All of the tests that you have undergone for assessment to participate in this study would normally have been done as part of your standard care, even if you were not participating in this study.

#### **Randomisation**

If you consent to participate in the study, you will be randomised into one of two treatment groups (or study arms).

Randomisation means that you are put into a group (or study arm) by chance. A computer program will choose which study arm you are allocated to. Neither you nor your doctor can choose the study arm you will be in. You will have an equal chance of being placed in either study Arm A or Arm B.

If you decide to participate in this study, you will be randomised to one of two different treatment regimes:

**Arm A:** Undergo surgery to remove your main colon or rectal cancer tumour and then have the standard treatment with chemotherapy or chemoradiotherapy for colorectal cancer at this institution as per your treating doctor's recommendation. You may also take part in other chemotherapy / chemoradiotherapy trials at the same time, including trials with experimental agents.

**Arm B:** Have the standard treatment with chemotherapy or chemoradiotherapy for colorectal cancer at this institution as per your treating doctor's recommendation. You may also take part in other chemotherapy / chemoradiotherapy trials at the same time, including trials with experimental agents. Surgery to remove the primary tumour will only occur if this becomes clinically indicated at a later stage.

#### **Pre-treatment**

Before undergoing surgery or chemotherapy/chemoradiotherapy treatment, you will be asked to undergo (or will have undergone already) the following examinations, tests or procedures which are part of regular care:

- History and physical examination (including height, weight and vital signs)
- Laboratory studies and blood tests

- Procedures, as ordered by your doctor, may include colonoscopy, rectal ultrasound, MRI, CT scans and x-rays.

Details of scans and procedures are described below:

A **colonoscopy** is performed to check the size and location of the tumour, and to obtain a sample of the tumour (biopsy). The procedure uses a camera on a flexible tube which is passed into the anus and up through the rectum and large bowel. You must not drink or eat anything for 4 hours before the procedure. The procedure itself takes about 30 to 60 minutes. The procedure is considered to be relatively painless and, at worst, associated with mild discomfort. Complications are rare, but can include bleeding and perforation of the bowel or rectal wall with the endoscope. Your doctor may also perform an endoscopic ultrasound, which may help to see the location and extent of the tumour. This is performed using an ultrasound probe on the endoscope.

A **rectal ultrasound** is a diagnostic test used to look inside your rectum. A flexible tube (Endoscope), with an ultrasound tip on it is passed into your rectum. The ultrasound tip, which is connected to a computer by the tube, uses soundwaves to make pictures of the inside of your rectum.

### **CT Scans**

You will be exposed to radiation during the CT scans. If a dye (contrast medium) is required to be injected for your scan, you may experience nausea, flushing, warmth, and a salty taste. Some patients have felt claustrophobic during this test. There is a possibility of an allergic reaction (anaphylaxis) to the contrast used in scans which, although rare, can be life threatening. If this occurs, drugs will be given to reverse the reaction. You should advise the radiologists if you are allergic to iodine.

An **MRI** scan uses powerful magnet and radio waves to produce images of your body. A loud tapping sound will be heard while the machine generates the images. It is important not to move at this time. The scan usually takes between 20 and 60 minutes. When the MRI scan is finished, you may immediately resume your normal activities. Some patients may require an injection of a dye into the vein to enhance the MRI images.

CT and MRI scans are painless. For these scans you will be positioned comfortably on a scan table and the examiner will talk with you via an intercom throughout the procedure in case you require anything. A strap will be placed across the body part to be scanned to prevent movement so that the scan will be clear.

You may experience some, all, or none of these side effects. The treatments used in this study may also involve unknown risk. You will be monitored closely for all side effects including any that are unexpected. If symptoms develop, the investigator will start appropriate treatment. You must tell the investigator about any new health problems that develop while you are participating in this study.

### **Pregnancy Test**

A pregnancy test will be performed on women of child-bearing potential.

### **Quality of Life Questionnaires**

You will also be asked to complete two questionnaires regarding quality of life which require about 15 minutes.

### **Surgery**

If randomised to **Arm A** you will receive surgery. There are two types of surgery and the best surgical method for you will be determined by your surgeon. This could be open laparotomy and resection of your colorectal cancer or laparoscopic resection of your colorectal cancer. You will then receive chemotherapy or chemoradiotherapy once you have recovered from surgery.

If randomised to **Arm B** you will receive chemotherapy or chemoradiotherapy and not undergo surgery unless this becomes clinically indicated at a later stage.

### **Open laparotomy and resection**

During open laparotomy, the surgeon makes an incision or cut in the abdomen and goes in through that cut to remove the tumour and lymph nodes from the bowel. A laparoscope (an instrument which is inserted through the abdominal wall to provide a view of the internal organs) also may be used during the open procedure.

### **Laparoscopic resection**

Laparoscopic resection is performed using small instruments on long handles introduced into the abdomen through small ports called trocars in 3 to 6 positions on the abdomen through incisions measuring 5 to 10 mm, under the guidance of a video camera. The tumour is removed through another incision (about 5 to 8 centimeters).

### **Post-surgery**

After surgery, you will be followed closely by your study doctor

### **Chemotherapy Treatment (Colon Cancer)**

This will involve standard treatment that you would receive if you were not participating in this study. The best treatment for you will be decided by your doctor.

### **Chemoradiotherapy Treatment (Rectal Cancer)**

This will involve standard treatment that you would receive if you were not participating in this study. The best treatment for you will be decided by your doctor.

### **Follow Up**

Follow up visits take place every month for six months and then every 3 months to a maximum of 2 years. You will not require any further tests that are not part of your normal routine care. You will be asked to complete two quality of life questionnaires at these visits. More frequent follow up and examinations may be requested if advised by your treating doctor.

## **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.

### **Risks related to surgery**

There are risks from any surgery and your doctor will discuss these with you. There are also risks associated with anaesthesia, which will be required for the surgery.

Everyone taking part in the study will be watched carefully for any complications or side effects. These may be mild or serious. Many side effects go away soon after surgery. Some side effects can be serious, long lasting, or may never go away. In some cases, surgery or other treatments may be needed to repair or correct side effects.

Prior to the surgery, your surgeon will discuss the details of the surgery and its risks as part of your usual clinical care. Your doctor can also discuss these issues with you throughout the trial.

### **Risks related to chemotherapy or chemoradiotherapy**

You will be given the standard treatment with chemotherapy or chemoradiotherapy for colorectal cancer at this institution as per your treating doctor's recommendation. This study does not detail any particular type of chemotherapy/chemoradiotherapy, that treatment decision is between your treating doctor and yourself.

There are risks from any chemotherapy and chemoradiotherapy and your doctor will discuss these with you. Prior to the receiving chemotherapy or radiotherapy, your doctor will discuss the details of

the treatment and its risks as part of your usual clinical care. Your doctor can also discuss these issues with you throughout the trial.

### **Risks related to blood sampling**

There may be some discomfort, swelling or bruising around the vein that was used to draw your blood. You may experience lightheadedness; and fainting at the time of blood drawing could occur. Infection at the blood drawing site may also occur.

### **Reproductive risks**

You should not be pregnant at the time of your surgery. After your surgery, if you require additional, non-surgical treatments such as chemotherapy or radiation, you should talk with your doctor regarding the risks of these therapies to a pregnancy or to fathering a child.

For more information about risks and side effects, ask your study doctor.

## **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.

In the event of loss or injury, the parties involved in the study agree to be bound by the Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial of Medicines Australia.

You may have the 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.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

## **7. Will I benefit from the study?**

We cannot guarantee that taking part in the trial will be of direct benefit to you, however the study aims to further medical knowledge, and through your participation in this study, greater treatment options in the future may help other patients with cancer of the colon or rectum.

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

Your study visits and procedures will be provided at no extra cost. You will not be paid for participation in this study.

The cancer centre responsible for your treatment will receive some payment from the AGITG 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 authorized representatives of the hospital's Human Research Ethics Committee, the study sponsor, the AGITG, staff from the NHMRC Clinical Trials Centre, University of Sydney and by regulatory authorities as required by law, for the purposes of verifying the study procedures or data. By signing the Consent

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Form, you authorise access to this confidential information to the relevant study personnel and regulatory authorities as noted above.

Your health status may also be followed up through Australian State-based Cancer Registries annually or as required.

#### **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 in peer-reviewed journals, presentation 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. 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:

#### **12. Who should I contact if I have concerns about the conduct of this study?**

This study has been approved by *[relevant HREC]*. Any person with concerns or complaints about the conduct of this study should contact *[name]* who is the person nominated by the Human Research Ethics Committee to receive complaints from research participants. You should contact them on *[number]* and quote *[HREC project number]*.

Name: *[This person should be someone independent of the study]*

Position:

Telephone:

**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.**

[Hospital letterhead]

Clinical Trial Name

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 my participation in this study will allow the researcher, the ethics committee and representatives of the AGITG and NHMRC Clinical Trials Centre to have access to my medical records, and I agree to this.

I understand that my health status may also be followed up through Australian state-based Cancer Registries annually or as required.

I also understand that the research study is strictly confidential.

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 (2007).

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

I hereby agree to participate in this research study.

NAME: .....

SIGNATURE: .....

DATE: .....

NAME OF INVESTIGATOR: .....

SIGNATURE OF INVESTIGATOR: .....

DATE: .....