Participant Information Sheet/Consent Form

Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Stage II Colon Cancer (DYNAMIC Study)

Protocol Number	WEHI-ctDNA-04
Project Organisation	The Walter and Eliza Hall Institute of Medical Research (WEHI)
Principal Investigator	*[Coordinating Principal Investigator/*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have Stage II bowel cancer (cancer has grown through the wall of the bowel but has not yet spread to the lymph nodes) that you recently had surgery to remove. The purpose of this study is to use samples of your blood and the tumour tissue removed as part of your surgery for a specific type of genetic testing to see if the results of this test can decide whether or not you will need chemotherapy more effectively than the standard of care practised at your institution.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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 genetic research?

Genes are made of DNA – the chemical structure carrying your genetic information that determines many human characteristics such as the colour of your eyes or hair.

Researchers study genes in order to understand why some people have a certain condition such as bowel cancer and why some people do not. Understanding a person's genes also may be able to explain why some people respond to a treatment, while others do not, or why some

people experience a side effect and others do not. The DNA of your cancer contains genes that are changed, or mutated, from your normal cells, which can in turn suggest that certain treatments work, while others may not have any benefit.

3 What is the purpose of this research?

The purpose of the research project is to see whether a genetic test called “circulating tumour DNA” is a more effective way of deciding whether or not patients will need additional post-surgery chemotherapy than the best standard of care at your institution. To do this, two-thirds of participants will be treated according to their “circulating tumour DNA” test results and one-third of participants will be treated according to the standard recommendation made by their doctors.

Your study doctors will have explained that your bowel cancer has been removed (resected) by your recent operation. However, there is a possibility that cancer cells too small to be seen by the naked eye or that appear on scans may have escaped before surgical removal of your tumour. Your doctor will routinely perform a microscopic examination of the bowel cancer tissue removed during your surgery to look for certain features (such as how far the cancer has grown into the wall of the bowel) to assess your risk of cancer recurrence. If your cancer has these features, which means there could be at a higher risk of recurrence, best standard of care practise sometimes recommends a three or six month course of chemotherapy in addition to the surgery, to reduce the risk of cancer from coming back. However, it is not yet known if this method of assessing your cancer is the most effective way to judge whether or not a patient will need additional chemotherapy.

The “circulating tumour DNA” blood test is based on the knowledge that bowel cancer cells have DNA mutations that are not present in normal cells. For some people, cancer-specific DNA can be found circulating in their bloodstream after the surgery to remove their bowel cancer, which may be evidence that some of the cancer cells have escaped before the bowel cancer has been removed. A previous study in patients with stage II bowel cancer has shown that people with “circulating tumour DNA” detected in their blood after surgery have a very high chance of the cancer coming back compared to those with no “circulating tumour DNA”. Therefore, this study is trying to see if a chemotherapy decision based on the presence (positive test) or absence (negative test) of “circulating tumour DNA” after surgery will be more effective at determining whether or not a patient will need additional post-surgery chemotherapy.

4 What does participation in this research involve?

The study consists of the following parts:

- A screening period where tests will be performed to find out whether or not this study is suitable for you.
- A treatment period during which you will receive your assigned treatment.
- A follow-up period where your progress will be monitored.

Screening

If you agree to take part in this research project, you will be asked to sign a consent form before any study-related procedures are performed. An archival sample of your tumour and normal tissue (a sample that was already collected during your surgery or a previous biopsy procedure) will be used for testing. You will also be required to have 30-60 mL of blood (1.5-3 tablespoons) taken from a vein in your arm approximately 4 and 7 weeks after your surgery for testing. After the collection of the week 4 blood sample, you will be randomised into one of the study groups described below. The samples of your tissue and blood for the “circulating tumour DNA” test will be analysed by Professor Bert Vogelstein’s laboratory at the Ludwig Center for Cancer Genetics & Therapeutics, Johns Hopkins University, Baltimore, Maryland, USA.

Because the circulating tumour DNA test looks for DNA mutations in the blood that have come from your cancer cells, your tumour sample will need to be tested to see what DNA mutations it contains. This is so the research team know what DNA mutations to look for in your blood sample. You will not be given the results of the genetic testing on your tumour tissue because it will not affect your current or future medical treatment.

Randomisation means that you are put into a group by chance, like the tossing of a coin. The reason randomised studies are done is because sometimes we do not know which way of treating a condition is best. To find out, we need to compare different ways of treating a condition. We put people into groups and give each group a different treatment. The results are compared to see if one is better. A computer program will choose which group you are allocated to. Neither you nor your study doctor can choose the group you will be in. 2 out of 3 participants will be placed in Group A and 1 out of 3 participants will be placed in Group B.

Group A – Chemotherapy decision according to circulating tumour DNA results (this is the experimental arm of the study)

Group B – Chemotherapy decision according to your doctor's recommendation (this is the best standard of care at your institution)

At screening, you will also have the following procedures:

- The Study Doctor will ask you about your health and your medical history
- You will have a physical exam performed
- You will be asked about your ability to perform your daily activities (ECOG performance status)
- A CT Scan will be performed (to detect any cancer recurrence) if you have not had one in the previous 8 weeks before you join this study. This is part of your normal care and the results of the CT scan will be accessed by study staff to assess your cancer status.

Treatment

If you are in Group A, the decision on whether you will receive chemotherapy or not will be based on the results of your "circulating tumour DNA" test. The results of this test will be given to your doctor within 10 weeks of your surgery.

If either the week 4 or week 7 blood tests are positive for circulating tumour DNA, then you will be treated with the standard of care chemotherapy for patients with your condition, which is 3 or 6 months of 5-fluorouracil (5-FU)/leucovorin chemotherapy or oxaliplatin/5-fluorouracil/leucovorin chemotherapy. Your doctor will decide the specific type, timing and frequency of your treatment. After finishing chemotherapy, you will enter the follow-up phase of the study.

During your chemotherapy, you will have a number of blood samples taken, as part of your standard of care, for routine safety tests and measurement of your serum CEA levels (an important tumour marker in the blood which can help your doctor evaluate your cancer). In addition to these routine blood tests, 30-60 mL of blood (1.5 - 3 tablespoons) will be collected every month while you are having chemotherapy, and at 4 weeks after completion of your chemotherapy.

If both the week 4 and week 7 blood tests are negative, then you will not receive any chemotherapy and will enter the follow-up phase of the study (as described below).

If you are in Group B, the "circulating tumour DNA" test results will not be given to your doctor and the decision on whether you will be treated with chemotherapy is based on your doctor's recommendation. If your doctor advises you to have chemotherapy, then you will be treated with the standard of care chemotherapy for patients with your condition, which is 3 or 6 months of 5-fluorouracil (5-FU)/leucovorin chemotherapy or oxaliplatin/5-fluorouracil/leucovorin chemotherapy. Your doctor will decide the specific type, timing and frequency of your treatment. Except for routine blood tests, no additional study-related blood will be collected during chemotherapy. After finishing chemotherapy, you will enter the follow-up phase of the study.

If your doctor does not recommend chemotherapy, then you will enter the follow-up phase of the study (as described below).

Follow-up:

For participants who received chemotherapy

You will have clinic visits every 3 months for 18 months (approximately 24 months after inclusion into the study), and then every 6 months for the next 3 years (approximately 5 years after inclusion into the study). CT scans to see if your cancer has spread to anywhere else in your body will also be performed every 6 months (from the time of your week 7 blood test) for 24 months, and at 3 years from inclusion into the study. This is part of your normal care and the results of the CT scan will be accessed by study staff to assess your cancer status.

At your clinic visits, you will have the following assessments:

- The Study Doctor will ask you about your health and your medical history
- You may have a physical exam performed
- Routine blood tests (including measurement of serum CEA)

For participants who did not receive chemotherapy

You will have clinic visits every 3 months for 24 months (approximately 24 months after inclusion into the study), then every 6 months for the next 3 years (approximately 5 years after inclusion into the study). CT scans to see if your cancer has spread to anywhere else in your body will also be performed every 6 months for 24 months, and at 3 years from inclusion into the study. This is part of your normal care and the results of the CT scan will be accessed by study staff to assess your cancer status.

At your clinic visits, you will have the following assessments:

- The Study Doctor will ask you about your health and your medical history
- You may have a physical exam performed
- Routine blood tests (including measurement of serum CEA)

After the five year follow-up period, all participants will be followed up by their doctor as per normal care. You may be contacted by your research doctor to ask about your general health, if your disease has worsened, and if you have started any new anti-cancer treatments.

For all participants, follow up colonoscopies will be performed on the advice of your surgeon, as per institutional standard of care.

Additional research with your coded study data and biological samples.

The Walter and Eliza Hall Institute (WEHI) and the Johns Hopkins University would like to use your study data, where a code replaces your name, and your remaining coded biological samples including blood and/or tumour tissue for additional medical and/or scientific research projects that are outside of the current study purpose and objectives. These samples may be kept for future use in research projects that are an extension of this research project. Alternatively we may use your sample for future research that is closely related to the original research project.

This may include research to gain more knowledge related to your disease and may be used to improve methods or design new methods for analysing, comparing or combining your study data with data from patients treated with other study medications, and may involve new ways of checking whether a treatment is beneficial to people with your disease, and other unexplored questions and research regarding the diagnosis and treatment of your disease.

The study doctor would like you to consider taking part in this study because you have bowel cancer. In the future, other doctors and scientists at this and other medical and research centres may use your tumour tissue and blood samples to learn about many different diseases and conditions. Their goal is to improve health outcomes and develop new treatments. The type of genetic research to be done as an extension of this research project is not testing that would result in information about a participant's risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the project. You will not be asked to give us health information about your relatives as part of this testing.

This additional use of your coded study data and biological samples is optional. This testing is for research purposes only. Any testing result/data generated from the additional research studies will belong to the WEHI and the Johns Hopkins University and will not become part of your medical record or be communicated to you. You do not have to agree to it. If you choose to take part, you can change your mind at any time. Your decision to refuse the use of your study data and biological samples for additional use will in no way impact your participation in the study. If you consent to this future use, you will be asked to sign an additional consent below.

Additional Research Opportunity: Patient Experience Questionnaire.
Having the circulating tumour DNA blood test for bowel cancer – What do patients think?

Alongside your blood testing there is an opportunity to participate in a patient experience project. The project is being done to explore how people feel about having the "circulating tumour DNA" blood test and additionally how people cope if they receive information from the blood test that is used to make decisions about receiving chemotherapy, or not.
Your opinion and personal experience and your answers will be very helpful for people who may be in this situation in the future.

By agreeing to take part in this project, you will be asked to complete 3 questionnaires on 3 occasions: 1) at the time of the 4 week circulating tumour DNA blood test 2) when a decision is made about whether your will receive chemotherapy, or not, 3) 9 months after the first questionnaire. This should take less than 30 minutes on each occasion and will be done when you attend for a clinic appointment.

The questionnaires will ask about how much you think about the cancer and the chance of it coming back in the future. In addition there are questions about your mood, functioning and quality of life. Everyone is asked exactly the same questions. Your personal details and answers are strictly confidential and will not be revealed to anyone outside the study.

At a later date you may also be asked to participate in a more detailed face-to-face interview in which you will be questioned by a researcher about your experience participating in the DYNAMIC study and having blood tests for circulating tumour DNA, as well as your feelings about this sort of information.

5 Other relevant information about the research project

A total of 450 people will participate in this study from approximately 20 hospitals across Australia and internationally. Approximately <INSERT DETAILS> participants will participate at <INSERT SITE NAME>.

There are no additional costs associated with participating in this research project, nor will you be paid. Your study visits and procedures will be provided at no extra cost. You will be required to pay for any medication needed to treat side effects from chemotherapy (e.g. anti-nausea medications).

Your study doctor will inform you about your personal test results where relevant. Results of the study will be provided to you, if you wish, by your study doctor.

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

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the <INSERT SITE NAME>.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you decide not to take part in this study, you will still be cared for by your doctor and will receive treatment for your cancer. These options may include chemotherapy, participation in other clinical trials or no treatment. Your study doctor will discuss these options with you 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?

It is possible that you will benefit in terms of your health and your disease by participating in this study but there is no guarantee for that. Information obtained from your participation may help other people in the future.

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

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Risks from Study Procedures

Blood Samples: Taking blood from a vein may cause bruising, bleeding at the site where the blood is taken, feeling faint, and some pain when the needle is inserted into your vein. Rarely, there may be a small blood clot or infection at the site of the needle puncture. The blood pressure cuff may also cause discomfort or bruising to the upper arm.

CT Scans: You will receive radiation when CTs scans are done. CT scans are routinely recommended every 6 to 12 months as per standard of care for at least 3 years to detect any cancer recurrence. In this study, you will be having CT scans every 6 months for the first 2 years and one CT scan in the third year. Some people may have a ‘closed in’ feeling while inside the machine. Intravenous contrast injected during the scan can feel uncomfortable The injection may make you sick to your stomach, pass out, you may experience pain, warmth, swelling, bruising, or get a small blood clot or infection at the injection site. You may get a rash or other signs of allergy from the injection. You should inform the physician or technologist if you have any history of allergies to, for example, seafood or certain medications, or if you have asthma, high blood sugar (or diabetes), heart problems, kidney problems, or thyroid problems, as all of these may increase your chances of having problems with the CT injection. Your physician or technologist can explain the procedure and risks in greater detail and clarify any concerns or questions.

Genetic Testing Risks.

In the majority of cases, the ctDNA testing being done in this study is not testing that would result in information about your risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the project. However, in the rare instance that the results of these tests do indicate that you or your family are more likely to develop a specific disease, your study doctor will inform you of this.

If this happens, you will be referred to the <INSERT SITE NAME>, where you will be able to discuss these results with a genetic counsellor at no cost to you, who will help you to understand the results and their implications to you and your future health. Your family members may also meet with this counsellor, if necessary.

In addition to this, any research results that could be of significance to you or your family will need to have the tests repeated and the results verified through an appropriate genetic service. This will involve having a blood sample taken and having it retested in a NATA accredited testing laboratory, and completing a family history questionnaire. This is standard practice for all patients receiving the results of genetic testing and would be provided free of charge to you. Before a test is repeated to verify a research finding, you will be informed about the possible risks involved for you.

In addition, there may be risks associated with this study that are presently unknown or unforeseeable.

10 What will happen to my test samples?

As part of this research trial, you will have a number of routine blood samples taken which are used to monitor your condition. These samples form part of your standard of care treatment. They are labelled with your information and will be processed at <INSERT SITE NAME>. These samples will not be stored for any extended period of time, and are not being used for any procedures other than those outlined in this document. Your blood samples will be destroyed by the local laboratory once the analysis is completed

Your samples and any paperwork accompanying the samples taken for the purposes of the "circulating tumour DNA" test will be labelled with a unique study code, not your name, address or hospital number and sent to Professor Bert Vogelstein's laboratory at the Ludwig Center for Cancer Genetics & Therapeutics, Johns Hopkins University, Baltimore, Maryland, USA.
If you consent to this the additional optional research discussed above, your blood and tumour samples or part thereof may be stored for up to 7 years from the end of the study at the Johns Hopkins University. Your previously collected tumour sample will also be kept at the Johns Hopkins University for a period of 7 years for the conduct of genetic research. Your tumour tissue and blood samples will be stored in a re-identifiable form at the Johns Hopkins University in the bank, Your samples and any paperwork accompanying the samples will be labelled with a unique study code, not your name, address or hospital number. Except for the study staff at the <INSERT SITE NAME>, this code makes sure that no-one handling your samples will be able to identify you. The samples will be destroyed at the end of this period.

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 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

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, although personal information already collected will be retained to ensure that the results of the research project can be

measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as the blood test under investigation here being shown not to be effective.

Part 2 How is the research project being conducted?

14 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Information collected about you during the trial will be kept at the Walter and Eliza Hall Institute of Medical Research.

Information about your participation in this research project may be recorded in your health records.

Your sample will have all identifiers (e.g. name and personal details) removed and replaced with a code. It will be possible to re-identify the sample as yours using the code. Your study doctor and relevant research staff will have the information to re-identify your samples. Your samples and data will not be released for any use without your prior consent, unless required by law.

Your health records and any information collected and stored by the study doctor during the research project may be reviewed for the purpose of verifying the procedures and the data. This review may be done by the ethics committee which approved this research project, regulatory authorities and authorised representatives of the Organization, the Walter and Eliza Hall Institute of Medical Research, <INSERT SITE NAME>, the Melbourne Health Human Research Ethics Committee or as required by law. In these circumstances, the Organization will not collect (i.e. record) your personal information. By signing the consent form, you authorise release of, or access to, this confidential information as noted above.

In accordance with relevant Australian and/or Victorian State privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

It is anticipated that the results of this research project 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 express permission.

We will not use your personal health information for a different research project without the permission of a Human Research Ethics Committee. Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the research project may be presented in public talks or written articles but information will not be presented that identifies the participant.

15 Complaints and compensation

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.

16 Who is organising and funding the research?

This research has been initiated by the study doctors, Associate Professor Peter Gibbs and Dr Jeanne Tie, and is funded by the National Health and Medical Research Council (NHMRC).
By taking part in this research project you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to The Walter and Eliza Hall Institute of Medical Research (WEHI). WEHI may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to WEHI.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to WEHI, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

<INSERT SITE NAME> will receive a payment from WEHI for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Melbourne Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

18 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on <INSERT CONTACT #> or any of the following people:

*List the names and contact phone numbers of other appropriate persons involved in the project including research nurses and study coordinators. The name and contact phone number of a person who can act as a 24-hour medical contact **must** be provided and clearly denoted.*

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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	Melbourne Health HREC
HREC Executive Officer	Ms Jessica Turner
Telephone	03 9342 8530

For matters relating to research at the site at which you are participating:

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

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

Consent Form

Title	Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Stage II Colon Cancer (DYNAMIC Study)
Protocol Number	WEHI-ctDNA-04
Project Organisation	The Walter and Eliza Hall Institute of Medical Research
Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location]*

Declaration by Participant

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 project without affecting my future health care.

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

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the <INSERT SITE NAME>concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that I can withdraw my consent to participate in this research project by completing a "Withdrawal of Consent" form. I can also specify whether I wish to have my tissue and blood samples, which has already collected and stored, deleted, destroyed or returned to me if it is still identifiable as mine.

Optional consent to additional research with your coded study data and biological samples
Please initial your choice below:
I DO consent to the storage and use of coded study data and biological samples taken from me for use in additional research as described in the relevant section of the Participant Information Sheet.

Initial_____ Date_____

I do NOT consent to the storage and use of coded study data and biological samples taken from me for use in additional research as described in the relevant section of the Participant Information Sheet.

Initial_____ Date_____

Optional consent: Patient Experience Questionnaire

Please initial your choice below:

1. I DO consent to participating in the patient questionnaire at the times described.

   Initial_____ Date_____

   I do NOT consent to participating in the patient questionnaire at the times described.

   Initial_____ Date_____

2. I DO consent to participating in an interview (if required) after completing the patient experience questionnaire if the researcher requires additional information.

   Initial_____ Date_____

   I do NOT consent to participating in an interview (if required) after completing the patient experience questionnaire if the researcher requires additional information.

   Initial_____ Date_____

Name of Participant **(please print)** _____

Signature _____ **Date** _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required*

Name of Witness* (please print) _____

Signature _____ **Date** _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older. Witness is required when the participant cannot read the document for him/herself.

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.

Form for Withdrawal of Participation

Title	Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Stage II Colon Cancer (DYNAMIC Study)
Protocol Number	WEHI-ctDNA-04
Project Sponsor	The Walter and Eliza Hall Institute of Medical Research
Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]*
Location	*[Location]*

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 <INSERT SITE NAME>

I request that all my tissue and blood samples collected and banked be deleted, destroyed or returned to me if it is still identifiable.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to 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.