*Insert Header with institution’s name or institution’s letterhead*

**Participant Information Sheet/Consent Form**

**Genetic Study** -*Adult providing own consent*

Monash Health

|  |  |
| --- | --- |
| **Title** | Australian Comprehensive Molecular Evaluation of Advanced Biliary Cancer Trial |
| **Short Title** | ACME ABC |
| **Protocol Number** | 1.0 |
| **Project Sponsor** | *Australasian Gastro-Intestinal Trials Group (AGITG)[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Daniel Croagh/*Principal Investigator]* |
| **Associate Investigator(s)***(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location]* |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. Your case has been reviewed by a multi-disciplinary team and unfortunately your biliary cancer is unsuitable for surgery because it is too advanced or has recurred. You will be asked to participate in a trial examining the feasibility and potential benefit of comprehensive genetic profiling of biliary cancer using endoscopic biopsies via EUS FNA or direct bile duct biopsies.

Participants will consent to undergo additional biopsies to be taken at subsequent endoscopic interventions for the routine diagnosis and management of their biliary cancer.

These extra biopsies will be taken during your routine endoscopic procedure and will be stored for genetic profiling. Typically, the biopsy will be done during an endoscopic ultrasound (EUS) or direct, targeted biopsies from within the bile duct (“cholangioscopic”). The biopsy will occur during procedures that are part of your routine care in the diagnosis and management of your advanced biliary cancer – no additional or extra procedure will be required.

You may have previously donated this tissue for research as part of the Pancreaticobiliary Cancer Biobank. If so, we will request permission to retrieve your biopsy sample and material from this biobank.

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. An interpreter may be used to assist you in understanding this project so that you can provide informed consent.

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 biliary 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.

Cancers can develop when the DNA in cells change significantly or mutate. This research will hopefully help contribute to future research into why certain treatments work with some cancers and not others.

**3 What is the purpose of this research?**

The purpose of this trial is to study whether comprehensive genetic profiling of biliary cancer may help improve outcomes for patients in the future by allowing us to develop more personalised treatment to the specific mutations within their tumour.

The purpose of the research project is to provide improve the diagnosis and treatment of bile duct cancers by analysing genetic material obtained from the tissue samples.

This research has been initiated by the study doctor, Dr Daniel Croagh and is being conducted by Monash Health and Monash University with sponsorship from Australasian Gastro-Intestinal Group (AGITG).

**4 What does participation in this research involve?**

Prior to being offered entry into the trial you have been screened to confirm that you are appropriate for this trial. This screening includes:

1. Suspected or confirmed advanced biliary cancer that cannot be managed with surgery as assessed by a team of specialists in a formal meeting that requires an EUS for tissue diagnosis

2. Confirmation that you have tissue sample already stored in the biobank or that you require an endoscopic procedure (EUS or ERCP) as part of the routine management of your condition. This provides us with an opportunity to obtain tissue from your suspected tumour that can be snap frozen.

3. Confirmation that you are in good physical health and are a candidate for chemotherapy.

If you agree to take part in this research project, an extra endoscopic biopsy will be taken at the

time of your routine endoscopic procedures and sent for processing and participation in the

study. If you have previously donated a tissue sample for biobanking this will be retrieved. In

addition, a sample of your blood may also be taken. Genetic material will be extracted from the

biliary cancer biopsy and or blood. If sufficient genetic material can be obtained from this extra

biopsy, it will be used for comprehensive genetic profiling of your tumour to assess whether

there are any targeted treatment options for your cancer.

You will need to meet with the study investigator(s) (at least) once to ensure that you have been fully informed about the nature of this research project and so that you can provide informed consent. If potential targeted treatment options are available, then you will be referred to be included as part of a broader study focusing on understanding the genetic changes in all types of cancer, the Molecular Oncology Screening Trial (MoST). Therefore, you will need to agree to participate in this overarching study too. A separate patient information and consent form will be provided to you.

Only after you have provided written informed consent, will your biopsy be retrieved, and an attempt made to extract sufficient genetic material to allow comprehensive genetic profiling of the cancer. If this is not possible you will be informed.

If the complete genetic analysis of your cancer is able to be successfully performed, you will be told by phone by your treating Doctor. This may occur some weeks after your entry into the trial. Your results will then be reviewed by a specially convened panel of clinicians including a molecular pathologist. Following this, a report will be issued to your treating oncologist who will discuss the results with you. Your ongoing care will continue to be provided by your local treating oncology team.

After this, no other visits are required unless the genetic analysis of your cancer reveals that you may have an inherited genetic predisposition to cancer. In this case, you will be offered an appointment with a clinical geneticist. This will involve having a blood sample taken and having it retested in an accredited testing laboratory. This is standard practice for all patients receiving the results of genetic testing and would be provided free of charge to you. Counselling may also be provided free of charge if appropriate or requested. Before a test is repeated to verify the research finding, you will be informed about the possible risks involved for you. This is especially important for individuals who are found to have an inherited genetic mutation that is associated with an increased risk of developing a disease such as cancer.

Your progress will be followed according the standard protocol as outlined in the MoST study. You will not need to be contacted for this.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. Therefore, we are undertaking a prospective cohort study (following a group forward in time) in which all patients with advanced biliary cancer who are fit for chemotherapy are offered the chance to participate in this trial. In this way, we will understand the overall likelihood of benefit from this approach to patients with biliary cancer.

There are no additional costs associated with participating in this research project, nor will you be paid. Any tests and medical care required as part of the research project will be provided to you free of charge.

It is possible that comprehensive genetic profiling of your cancer may reveal that a specific treatment may be of benefit to you. If your treating oncologist believes that you may benefit from this treatment and it is unavailable on the pharmaceutical benefits scheme, you may be able to access this in the context of a clinical trial or on a compassionate basis. Although we will attempt to facilitate this, we cannot guarantee that this will be possible, and you may choose to pay for this treatment if you feel that this is worthwhile.

**5 What do I have to do?**

Apart from agreeing to participate in this study and the MoST study, allowing access to your biopsy sample and providing a sample of your blood at the time of entry into the trial, there are no other requirements for participating in this trial. If you are requiring a change of stent as part of your care then potentially your specialist may request to obtain an additional biopsy as part of that procedure at the time.

**6 Other relevant information about the research project**

All participants in this trial will be offered an attempt at comprehensive genetic profiling of their cancer. The goal is for at least 50-75 (hopefully 100) people with advanced biliary cancer will be enrolled in the trial. The trial is also open at several other sites in Australia, as part of a co-ordinated multi-centre study.

This trial builds on previous work arising from the Pancreaticobiliary Cancer Biobank which has demonstrated that it is possible to perform comprehensive genetic profiling in patients with pancreatic and biliary cancers. The purpose of this trial is to test whether this could be offered as part of routine clinical care and in what proportion of patients, this is likely to be successful.

**7 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 decisions whether to take part or not to take part, and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[Institution]*.

**8 What are the possible benefits of taking part?**

You will be contacted if the testing shows important information about you, and you will be asked if you wish to know the results. The results may be important to you as they may provide:

* Information about the genetic mutations within your cancer that may be amenable to specific treatment (about 10%)
* Facilitate access to potential treatments that might be suitable for you (about 5%)

Everyone has a different perspective on their health. Some people do not wish to know their possible chance of passing on a gene problem to their family, but equally some people may wish to know. The study may discover information about such risk of an inherited condition in about 5% of participants. This may influence or impact on your decision about planning a family depending on the information found.

If the testing shows important information that may impact or affect your relatives then disclosure of this to the relatives may be encouraged. You may wish to do this yourself or ask the researchers to contact them on your behalf.

Should you inform your relatives and they wish to know your results, expert counselling will be provided by a genetic counsellor to explain what the results mean for you and to support you as necessary. It will be necessary to refer you for re-testing by genetic services outside this research project.

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

Endoscopic procedures part of your routine care have potential risks or complications. This study involves taking an additional biopsy taken at the time of your required routine endoscopic procedure.

An additional biopsy does expose you to a very small risk of complications. With respect to EUS-FNA an additional pass of the FNA needle poses a very small risk of bleeding. With respect to direct biopsy within the bile duct, the risk of additional biopsies is negligible. Overall, the additional risk associated with the extra biopsies for this study is very small that it will be impossible to distinguish from the inherent risk of the routine diagnostic procedure itself.

Genetic testing may raise important issues as mentioned in the previous section. Although few may be expected to arise, your awareness of this is important for you to think about and carefully consider before agreeing to participate.

Learning about such results might affect you and your family emotionally. In some cases, the result may give certainty that you do not have a disease but could also create uncertainty or be upsetting; if for instance, the test indicates an increased risk of developing a disease which has no known prevention, treatment or cure.

It is important to understand that results from genetic research will usually not indicate that you have a disease or disorder, or whether you will develop it. Research may only show that you have an increased risk of developing a disease or disorder. Even then, there is no guarantee that you will develop the condition or any indication of the likely age you might get the disease or how serious the disease might be.

You may learn information from your test result about inherited diseases or disorders that may affect others, such as your brothers or sisters. This could interfere with family relationships. You may be faced with the decision to make the family aware of the existence of genetic information. Family members may or may not wish to know this information.

Any research results that could be of significance to you or your family will need to have the tests repeated and the results verified. This will involve having a blood sample taken and having it retested in an accredited testing laboratory. This is standard practice for all patients receiving the results of genetic testing and would be provided free of charge to you. Counselling may also be provided free of charge if it is appropriate. Before a test is repeated to verify the research finding, you will be informed about the possible risks involved for you. This is especially important for individuals who are found to have a genetic mutation that is associated with an increased risk of developing a disease such as cancer or heart disease.

Statutory or contractual duties may require you to disclose results of genetic tests or analysis to third parties (for example, insurance companies, employers, financial and educational institutions), particularly where results provide information about health prospects. If the results of your genetic tests are not available to you or you choose not to have the results given to you, then your future requests for insurance will not be affected by participating in this research.

If you do obtain the results of your genetic tests, you may then be obliged to disclose this on any future application for insurance or employment should it be requested.

**10 What will happen to my test samples?**

We would like to store your tissue samples and blood 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 or as a control tissue sample. Further information can be found in this document’s section on banking.

**11 What is the potential impact on my family if I take part?**

You may be asked health information about your relatives such as if anyone else in the family has had biliary cancer or another type of cancer. Any information you give us will be kept confidential. We will not contact your relatives without your permission. We may discuss with you the possibility of including your relatives in the research project in the future.

If the research discovers that one of your family members may be at risk of a life-threatening or serious illness for which treatment is available or pending, this information may, with the prior approval of a Human Research Ethics Committee, be offered by the study doctor to the family member, even if you do not consent to this. Such discoveries are made from the genetic analysis of the study participant’s tissue sample only (not from other family members).

**12 Will I be given the results of the research project?**

Your genetic test results will be made available to your treating team and to you should you wish. It is your decision whether you wish to be informed of your results. Before you decide if you wish to have your genetic test results, it is important that you read the information above regarding risks carefully so that you can make an informed decision.

If you decide to see your genetic test results, and you are found to have an inherited genetic predisposition to cancer (~5% chance), a specialist clinical geneticists and genetic counsellors will speak with you and assist you through the process. This will be at no cost to you.

Genetic information is complex and can be influenced by other factors including environment and lifestyle. Because genetic information is complex and sensitive, the results should be discussed with a clinical geneticist and genetic counsellor who can give you details that are relevant to you, answer your questions and discuss your concerns.

In the future, if during the course of this research project we discover new information that is important for your health care, you will be asked whether you wish to receive the results (this may require you to have the test repeated in a clinical laboratory). If you agree, we may contact you if such a situation arises.

**13 Will drug or biotechnology companies be able to use my sample for profit in the future?**

There is the possibility that this research may result in commercially viable technology or treatments. However, you will not be able to claim financial benefit from any discoveries arising from the use of your biliary cancer biopsy or blood specimen.

**14 Banking (Long term storage of samples)**

“Banking” is storing health information and/or blood or tissue for future research studies. A “bank” is the place where the health information and/or blood or tissue is stored. You may have previously given consent for biobanking of your biliary cancer. As part of this study your blood will be stored as re-identifiable specimen(s).

The study doctor seeks your permission to store your blood and excess diagnostic biopsy material for future research. The study doctor would like you to consider taking part in this bank because you have advanced biliary cancer. In the future, other doctors and scientists at this and other medical and research centres may use blood specimen to learn about other aspects of biliary cancer and its management. Their goal is to improve health outcomes and develop new treatments.

The study doctor will store your blood taken at the time of entry into this trial. The blood will be stored in the Pancreaticobiliary Cancer Biobankalong with samples of many other people. Your blood will be stored for at least 15 years after the research project is over, which we expect will be 2040.The purpose of storing your blood in a bank is to answer questions in the future, so we expect to keep your blood for a long time.

Your blood sample will be identifiable by a code; it can be identified as yours even though the bank does not know your identity. You can have it removed or destroyed by contacting the study doctor, ***DOCTOR NAME*** at ***ADDRESS***.

**15 What are the possible benefits of banking the biopsy sample and my blood?**

There is no direct benefit to you. Other people might benefit if researchers learn more by using your banked biopsy material or blood.

**16 What are the possible risks and disadvantages of banking?**

There is no extra physical risk to you as part of the research, given that we are using obtaining an initial additional biopsy at the time of your diagnostic procedure. The biopsy fluid material that would normally be discarded will be kept and stored for potential future testing. The blood sample you provide will be stored in a re-identifiable form in the Pancreaticobiliary Cancer Biobank. The risk of your identity being inadvertently revealed is extremely remote as samples are stored in a de-identified way and access to re-identifying information is only permitted following approval by the human research ethics committee at Monash Health.

**17 Will I be informed of results of future research using my biospecimen?**

You will not be informed about the results of future research as it will not impact on your health or treatment.

**18 Banking of Health Information**

The health information we will collect and store in the Pancreaticobiliary Cancer Biobank for this research project includes, demographic details, the stage of your cancer, the data from your medical imaging procedures, the outcome of the genetic testing and molecular tumour board review, and the nature of any treatments that you receive.

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 yourself.

If you consent to this study, your medical records at Monash Health or participating site may be accessed by a study Doctor to gather medical information relevant to your cancer diagnosis. This includes the date of diagnosis, age at diagnosis, treatments received and what benefit was derived from these treatments. All information recorded will have personal information removed/deidentified to protect your confidentiality.

**Part 2 How is the research project being conducted?**

**19 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. Data will be stored securely in re-identifiable form in a secure RedCap database through Monash University. Monash University implements a defence in depth approach to information security and employs a multitude of controls to protect our infrastructure and data. These controls are regularly audited to ensure they meet global best practices. Data collected will be stored on University managed secure and resilient infrastructure located in Australia that complies with all applicable data protection and privacy obligations.

Your personal information will be only used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Your data will be stored indefinitely.

In the future, the results from the comprehensive genetic profiling of your biopsy and blood may be given to researchers as part of the search for a genetic cause of biliary cancer or other research purposes. The samples will be labelled as described in Part 1 of this document.

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 information and the code will be held in the Pancreaticobiliary Cancer Biobank. Your samples will be stored in the Pancreaticobiliary Cancer Biobank. 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 Sponsor, Daniel Croagh, this organisation, Monash Health or as required by law. In these circumstances, the Sponsor 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 Victorian 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 medical 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.

**20 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.

You do not give up any legal rights to compensation by participating in this research project.

**21 Who is organising and funding the research?**

This research project is being conducted by Dr Daniel Croagh in collaboration with the Pancreatiocobiliary Cancer Biobank. Funding has been provided by the AGITG and is supported by the MoST study.

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 Monash University. Monash University 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.

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

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

**22 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 Monash Health. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**23 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, Dr Daniel Croagh on (03) 9594 4605.

 **Clinical contact person**

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

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

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *[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 name | Monash Health |
| Telephone | 03 9594 4605 |
| Email | *research@monashhealth.org* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

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

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

**Consent Form**

|  |  |
| --- | --- |
| **Title** | Australian Comprehensive Molecular Evaluation of Advanced Biliary Cancer Trial |
| **Short Title** | ACME ABC  |
| **Protocol Number** | 1.0 |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/****Principal Investigator** | Dr Daniel Croagh*/**Principal Investigator]* |
| **Associate Investigator(s)***(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location where the research will be conducted]* |

**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 *[Name of Institution]* concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

In respect to receiving information in relation to my genetic materials:

If research with my DNA and/or tissue reveals some other medical condition relating to me or my family for which treatment is available or pending:

|  |  |
| --- | --- |
| a. I wish to be informed | Yes [ ]  No [ ]  |
| b. I wish for affected family members to be informed and I give my consent for the researcher to approach my relatives on my behalf | Yes [ ]  No [ ]  |

In respect to the storage and use of my genetic samples, I give permission for the use of my DNA and/or tissue for the purpose of:

|  |  |
| --- | --- |
| 1. this research project only | Yes [ ]  No [ ]  |
| 2. this research project and any closely related future research projects | Yes [ ]  No [ ]  |
| 3. future research projects that may or may not be related to this research project | Yes [ ]  No [ ]  |

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 myblood, which has already collected and stored, deleted, destroyed or returned to me if it is still identifiable as mine.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

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|  |
|  | 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\* to Participant’s Signature (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.

**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.

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|  |
|  | 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**

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant’s decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.*

|  |  |
| --- | --- |
| **Title** | Australian Comprehensive Molecular Evaluation of Advanced Biliary Cancer Trial |
| **Short Title** | ACME ABC |
| **Protocol Number** | 1.0 |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/****Principal Investigator** | Dr Daniel Croagh*/**Principal Investigator]* |
| **Associate Investigator(s)***(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location where the research will be conducted]* |

**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 *[Institution]*

*Optional paragraph:*

I request that all my bloodcollected 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.