SAMPLE Informed Consent Form

A MULTICENTRE RANDOMIZED PHASE II TRIAL COMPARING NAB-PACLITAXEL TO PACLITAXEL IN PATIENTS WITH ADVANCED UROTHELIAL CANCER PROGRESSING ON OR AFTER A PLATINUM CONTAINING REGIMEN

Trial Code: BL.12

Researcher: Dr. _____

Sponsor: NCIC Clinical Trials Group

Le formulaire de consentement est disponible en français sur demande.

Note to centre: If an REB approved French consent is not used at your institution you should remove the above statement.

Emergency Contact Number (24 hours / 7 days a week): _____

Non-Emergency contact numbers are noted at the end of this document under the section heading “Contacts”.

INTRODUCTION

You are being invited to participate in a clinical trial (a type of study that involves research). Clinical trials only include participants who choose to take part. You are invited to participate in this trial because you have urothelial cancer for which you have already received chemotherapy. Your urothelial cancer has now progressed, which means it has worsened or relapsed (come back), and cannot be cured by radiation treatment or surgery. This consent form provides you with information to help you make an informed choice. Please read this document carefully and take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study later will not result in any penalty or any loss of benefits to which you are entitled. If you decide to stop participating in the study, your doctor will discuss other options with you and continue to treat you with the best means available.

Nab-paclitaxel is a formulation of the chemotherapeutic drug paclitaxel that is combined with a human protein called albumin. In Canada, nab-paclitaxel is currently approved for the treatment of metastatic breast cancer. This drug has been tested in other cancers and has shown promising activity in lung cancer, melanoma and pancreatic cancer. Information from research studies suggests that nab-paclitaxel may be a useful treatment for urothelial cancer.

Health Canada, the regulatory body that oversees the use of drugs in Canada, has not approved the sale or use of nab-paclitaxel or paclitaxel to treat urothelial cancer, although they have allowed its use in this study. The research ethics board, who oversees the ethical conduct of research involving humans in your hospital/clinic, has reviewed and accepted this study.

PURPOSE

The purpose of this study is to compare the effects on you and your urothelial cancer of nab-paclitaxel compared to paclitaxel to treat this disease.

This research is being done because currently there is no effective treatment for urothelial cancer that has progressed after prior chemotherapy.

Note to centre, please adjust this section to reflect standard or usual treatment in accordance with your local policy.

ALTERNATIVE TREATMENTS

You do not have to take part in this study in order to receive treatment/care; other options may include, but are not limited to:

- no therapy at this time
- palliative care or Best Supportive Care (BSC). This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Best Supportive Care tries to keep you as active and comfortable as possible.
- other experimental studies may be available if you do not take part in this study

Please talk to your study doctor or usual cancer doctor (if different from the study doctor) about the known benefits and risks of these other options before you decide to take part in this study. Your cancer doctor can also discuss with you what will happen if you decide not to undertake any treatment at this time.

EXPECTED NUMBER OF PARTICIPANTS

About 199 people from Canada, Australia and New Zealand will take part in this study.

This study should take three and a half years to complete and the results should be known in about five years.

Your study doctor will be informed of the results of this study once they are known.

ASSIGNMENT TO A GROUP

If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either group. Neither you nor your doctor can choose what group you will be in.

You will be told which treatment you are to get.

For **Group 1** (EXPERIMENTAL ARM): Nab-Paclitaxel

If you are randomized to Group 1 you will be given the experimental drug nab-paclitaxel. Nab-paclitaxel will be given into one of your veins by needle every 21 days. The procedure will take about 1 hour. You will continue on drug indefinitely as long as you are responding and able to tolerate the drug well. The dose may be changed if you have side effects.

Group 2 (CONTROL ARM): Paclitaxel

If you are randomized to Group 2 you will be given the experimental drug paclitaxel. Paclitaxel will be given into one of your veins by needle every 21 days. The procedure will take about 4 hours. You will continue on drug indefinitely as long as you are responding and able to tolerate the drug well. The dose may be changed if you have side effects.

No matter which Group you are randomized to, antiemetics, drugs that are effective against vomiting and nausea, and other medications, such as steroids, may be given before you receive your treatment to try to prevent some of the possible side effects from treatment.

NON-EXPERIMENTAL PROCEDURES (Screening Procedures)

The following tests will be done *at* the hospital or clinic to make sure that you are eligible for this study:

Some of these tests may have been done as part of your standard care, in which case the results of those tests may be used.

- blood tests
- physical examination
- pregnancy test
- chest x-ray
- magnetic resonance imaging (MRI) – a scan that uses a strong magnet to produce pictures of areas inside the body such as organs and other tissue, and inside of bones.
- computed tomography (CT) scan- a series of x-rays of the body from many angles that are turned into 3-dimensional pictures on a screen. CT scans often involve injecting a dye into your vein.

- bone scan

Many of these tests will also be repeated during the study. Some of these tests may be done more frequently than if you were not taking part in this study.

QUESTIONNAIRES

You will be provided with questionnaires before starting this study, on days 5 to 7 of cycles 1 and 2 (one cycle equals every 21 days), day 1 of cycle 4 and then on day 1 of every 4 cycles while you are receiving study treatment. If you come off study treatment, then you will be given the questionnaire at every 6 week clinic visit until your cancer gets worse and/or your doctor decides to give you another treatment. The purposes of these questionnaires are to understand how your treatment and illness affects your quality of life. These questionnaires will each take about 10 minutes to complete.

In addition, you will be asked to complete a health and demographic questionnaire around the time you start treatment. This questionnaire takes around 20 minutes to complete. The purpose of this questionnaire is to help researchers understand how different factors (such as your family history, and information about your life), may relate to bladder cancer. This includes trying to understand which factors might influence the likelihood of getting bladder cancer, predict who can benefit most from or how people respond to treatment, and effect quality of life. This information may also be used to help understand how the trial results relate to the general population. These questionnaires ask for information on where you were born, your medical history, your family's medical history, information on your exposure to cigarettes and alcohol use, physical activity, past and present occupations, educational history, and marital status. This questionnaire also collects information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different medications.The identification on the questionnaire will include your participant code, which includes your initials. The questionnaires will be sent to NCIC Clinical Trials Group.

The information you provide is for research purposes only and will remain strictly confidential. Some of the questions are personal; you can choose not to answer these if you wish. The individuals (e.g. doctors, nurses, etc.) who are not involved in the study will not review your responses to these questions—if you wish them to know this information please bring it to their attention.

Optional Sample Collection and Banking

The researchers doing this study are interested in doing additional research now or in the future on the samples collected from you. You will be given an additional optional study consent form to read and sign if you wish to give permission for the samples to be banked (stored) for future research purposes. You may decide not to participate in the "optional" study and still participate in this main study.

RESPONSIBILITIES

If you choose to participate in this study, you will be expected to:

- Tell your study doctor about your current medical conditions;
- Tell your study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbals, and check with your study doctor before starting, stopping or changing any of these. This is for your safety as these may interact with the treatment you receive on this study. Tell your study doctor if you are thinking about participating on another research study;
- Return any questionnaires to the study doctor that you take home to complete;
- Tell your study doctor if you become pregnant or father a child while participating on this study;
- Patients should not use St. John's Wort as an herbal medicine during study treatment.

LENGTH OF PARTICIPATION

Your treatment with nab-paclitaxel, if you are randomized to Group 1 (Experimental Arm), or paclitaxel, if you are randomized to Group 2 (Control Arm), will continue until your doctor feels you are no longer benefiting from your treatment.

***Note to centres**: Centres should indicate the overall length of time required beyond that of the standard or usual care at the Centre - specifying the difference in the number of visits and the length of time for each visit plus the time needed to complete questionnaires or diaries.*

No matter which group you are randomized to, and even if you stop treatment early, we would like to keep track of your health for the rest of your life to look at the long-term effects of your participation on this study.

EARLY END TO PARTICIPATION

The researchers can take you off the study treatment early for reasons such as:

- The treatment does not work for you and your cancer gets worse.
- You are unable to tolerate the study treatment.
- New information shows that the study treatment is no longer in your best interest.
- Your doctor no longer feels this is the best treatment for you.
- The NCIC CTG decides to stop the study.
- If you become pregnant.

RISKS OF PARTICIPATION

Participating on this study will put you at risk for the side effects listed below. You should discuss these with your doctor. As with any experimental drug additional unexpected and sometimes serious side effects are a possibility.

Your doctor will watch you closely to see if you have side effects. When possible, other drugs will be given to you to make side effects less serious and more tolerable. Many side effects go away shortly after chemotherapy is stopped but in some cases side effects can be serious, long-lasting, permanent, or may even cause death.

Risks and side effects related to the experimental drug NAB-PACLITAXEL we are studying include:

Very likely (21% or more):

- nausea and vomiting (If needed, nausea medication will be prescribed before and during treatment.)
- lowering of blood cell counts (red cells, white cells and platelets) which could increase your risk of developing anemia, infection or bleeding/ bruising
- diarrhea
- constipation
- anorexia
- dehydration
- hair loss
- fatigue and/or tiredness
- general weakness, loss of strength
- joint and/or muscle pain
- infection including pneumonia, blood infection (sepsis), shingles, urinary tract infection, upper respiratory infection, sore throat, cold sores, sinusitis, yeast infection of the mouth (thrush). Rarely infections may be serious and or life threatening

- abnormal heart rhythm seen in electrocardiogram (ECG) which could rarely be a sign of a more severe heart problem
- numbness, tingling in hands and feet, possibly with strength reduced (may be severe)
- abnormal liver function as seen by blood tests (in rare cases this can be life threatening)

Less likely (5 – 20%):
- fever
- shortness of breath
- cough
- rash or itchiness
- swelling of legs, arms, hands or feet due to accumulation of fluid
- inflammation or sores in the mouth and lining of the intestine which could become severe
- low blood pressure (hypotension)
- changes in vision including blurred vision and less likely, inflammation of the cornea or fluid accumulation leading to decreased vision. These are generally reversible but rarely can lead to permanent loss of vision.

Rarely (1 – 4%):
- pain (itching, swelling, redness) at the injection and/or catheter sites
- nail changes (changes in colour of nail bed)
- allergic reactions (swelling of the face, lips or tongue, difficulty breathing, rash, flushing or fainting) (very rarely can be life threatening).
- abnormal heart beat (faster, slower, or irregular), chest pain or heart attack or heart failure.
- high blood pressure (hypertension)
- abnormal kidney function seen by blood tests
- inflammation of the colon
- blockage of the intestine, formation of a hole in the lining of the intestine
- inflammation of the pancreas
- severe life threatening damage to the lungs which can lead to inflammation and fluid in the lungs and scarring of lung tissue
- poor functioning of your brain due to changes in the salts in your blood.
- stroke
- confusion, dizziness/light-headedness
- depression, mood changes
- weakness or loss of function of a muscle caused by damage to a nerve
- serious skin disorders such as Stevens-Johnson syndrome, a condition that affects your skin and mucous membranes which begins with flu-like symptoms followed by a painful red or purplish rash that spreads and blisters and may be followed by shedding of the top layer of skin

Risks and side effects related to the experimental drug <u>PACLITAXEL</u> we are studying include:

Very likely (21% or more):
- nausea and vomiting (If needed, nausea medication will be prescribed before and during treatment.)
- diarrhea

- lowering of blood cell counts (red cells, white cells and platelets) which could increase your risk of developing anemia, infection or bleeding/ bruising
- inflammation or sores in the mouth and lining of the intestine which could become severe
- allergic reactions (swelling of the face, lips or tongue, difficulty breathing, shortness of breath, a fast heart rate, changes in blood pressure, excessive sweating, chills, pain, rash, flushing or fainting).
- numbness, tingling in hands and feet, possibly with strength reduced (may be severe)
- fatigue and/or tiredness
- general weakness, loss of strength
- joint and/or muscle pain
- infection including pneumonia, blood infection (sepsis), shingles, urinary tract infection, upper respiratory infection, sore throat, cold sores, sinusitis, yeast infection of the mouth (thrush). Rarely infections may be serious and/or life threatening.
- abnormal heart rhythm seen in electrocardiogram (ECG) which could rarely be a sign of a more severe heart problem
- abnormal liver function as seen by blood tests (in rare cases this can be life threatening)
- hair loss

Less likely (5 – 20%):

- low blood pressure (hypotension)
- fever
- constipation
- abnormal kidney function seen by blood tests
- pain (itching, swelling, redness) at the injection and/or catheter sites
- swelling of legs, arms, hands or feet due to accumulation of fluid
- changes in vision including blurred vision and less likely, inflammation of the cornea or fluid accumulation leading to decreased vision. These are generally reversible but rarely can lead to permanent loss of vision.

Rarely (1 – 4%):

- abnormal heart beat (faster, slower, or irregular), chest pain or heart attack or heart failure.
- fainting
- high blood pressure (hypertension)
- nail changes (changes in colour of nail bed)
- inflammation of the colon
- blockage of the intestine, formation of a hole in the lining of the intestine
- inflammation of the pancreas
- severe life threatening damage to the lungs which can lead to inflammation and fluid in the lungs and scarring of lung tissue
- hearing loss
- weakness or loss of function of a muscle caused by damage to a nerve
- abnormal brain function, seizures
- dehydration
- serious skin disorders such as Stevens-Johnson syndrome, a condition that affects your skin and mucous membranes which begins with flu-like symptoms followed by a painful red or purplish rash that spreads and blisters and may be followed by shedding of the top layer of skin

It is possible that other drugs (prescription and non-prescription drugs), vitamins, or herbals can interact with the drugs used in this study. This can result in either the drugs not working as expected or result in severe side effects.

Long term effects of the chemotherapy used in this study include an increased risk of developing other cancers.

Some cancer treatments such as chemotherapy (including nab-paclitaxel and paclitaxel) or other drugs increase the risk of blood clots in your veins. Please tell your doctor if you have any new swelling in a leg or arm or have a sudden problem with your breathing. These may be signs of a clot forming or a clot moving to your lungs. Rarely, blood clots can be fatal.

A Data Safety Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

REPRODUCTIVE RISKS

Nab-paclitaxel and paclitaxel may harm an unborn baby (fetus). You must not become pregnant or father a baby while taking nab-paclitaxel and paclitaxel and for 30 days after the last dose. Your study doctor will discuss methods with you to ensure that you do not become pregnant or father a baby during the study.

Women should not nurse (breastfeed) a baby while taking study treatment and for 30 days after the last dose because the drugs used in this study might be present in breast milk and could be harmful to a baby.

If you become pregnant or father a child during this study or for 30 days after you stop taking the study drug, then you should immediately notify your study doctor. Your study doctor will let the sponsor know about the pregnancy.

If you become pregnant, the researchers or sponsors for this study will access information on the outcome of the pregnancy (the child's health etc.). This information will be gathered from your medical/study record. This may also involve contacting you to ask about the health of your child. We may also ask to contact the child's father to get information related to the pregnancy. If you become pregnant and do not want the researchers/sponsors to collect this information, you must let your study doctor know.

If you father a child, the researchers or sponsor for this study will ask to contact the child's mother to collect information on the outcome of the pregnancy (the child's health, etc.). Your partner will be given a separate consent document to sign to give permission for the collection of this information, if a pregnancy should happen.

Some of the drugs used in this study may make you unable to have children in the future. Your study doctor will discuss this with you.

BENEFITS

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will help other patients in the future.

CONFIDENTIALITY

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Qualified representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, for quality assurance (to check that the information collected for the study is correct and follows proper laws and guidelines).

- NCIC Clinical Trials Group (NCIC CTG), the research group coordinating this study
- The research ethics board who oversees the ethical conduct of this study in your hospital/clinic
- Celgene, the company which makes the drug nab-paclitaxel
- Health Canada (because they oversee the use of drugs in Canada)
- Other regulatory authorities (because they oversee the use of new drugs in other countries)

Qualified representatives of the following organizations, in addition to those listed above, may receive information related to the study from your medical/clinical study records, containing your participant code, initials, sex, and date of birth, for quality assurance and data analysis.

***Note to centres**: If there is planned disclosure of personal identifiers, or if they are used on any research-related information/documents, or if they are part of the unique identifier, this must be justified in the REB application and approved. Please ensure that you are aware of your local REB's and your centre's policies with respect to the disclosure of personal identifiers; specifically date of birth and initials. If the REB or the centre mandates the disclosure only of partial date of birth (year/month), and/or of scrambled/coded initials, this will be accepted by NCIC CTG.*

Studies involving humans now routinely collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. Providing information on your race or ethnic origin is voluntary. Your name or other information that may identify you will not be used:

- Australian Therapeutic Goods Administration (because they oversee the use of drugs in Australia)
- New Zealand Ministry of Health (because they oversee the use of drugs in New Zealand)
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
- NHMRC Clinical Trials Centre

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of drugs used in this research.

All of the organizations listed in the above confidentiality sections are required to have strict policies and procedures to keep the information they see or receive about you confidential, except where disclosure may be required by law. The study doctor will ensure that any personal health information collected for this study is kept in a secure and confidential location as required by law. There are federal and provincial laws that these organizations must comply with to protect your privacy.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

Your family doctor will be informed that you are taking part in a study so that your study doctor and your family doctor can provide proper medical care.

Any information sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data and/or samples, that is transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

Registration of Clinical Trials

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

COSTS

The study drug, nab-paclitaxel, will be given to you free of charge unless the following occurs:

- You stop participating on this study.
- The drug is no longer provided for this study.
    - If this occurs, you or your insurance company may have to pay for the drug. Your study doctor will discuss these options with you, as well what will happen if there is no more drug available.

If a problem with getting nab-paclitaxel occurs, your study doctor will talk to you about these options.

The costs of your medical treatment will be paid for by your provincial medical plan to the extent that such coverage is available. There may be extra costs that are not covered by your medical plan that you will have to pay yourself, some examples may be physiotherapy or certain pain medications.

Taking part in this study may result in added costs to you (i.e. transportation, parking, meals, or unpaid leave from work). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the hospital more often than if you were not participating in this study

COMPENSATION

You will not be paid for taking part in this study.

It is possible that the research conducted using your study data may eventually lead to the development of new diagnostic tests, new drugs or other commercial products. There are no plans to provide payment to you if this happens.

In the case of research-related side effects or injury, medical care will be provided by your doctor or you will be referred for appropriate medical care.

Although no funds have been set aside to compensate you in the event of injury or illness related to the study treatment or procedures, you do not give up any of your legal rights for compensation by signing this form. This consent form does not relieve the investigator, the hospital, the sponsor, and their agents from their legal and professional responsibilities.

RIGHTS

If you decide to stop participating in the study, your doctor will discuss other options with you and continue to treat you with the best means available.

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You may withdraw your permission to use your personal health information for this study at any time by letting the study doctor know. However, this would also mean that you withdraw from the study. Your study data that was recorded before you withdrew will be used but no information will be collected or sent to the sponsor after you withdraw your permission.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

CONFLICT OF INTEREST

Note to centres: Please include details of any actual or potential conflict of interest concerning this study.

This centre is receiving funds from the NCIC Clinical Trials Group to help offset the costs of conducting this research. NCIC CTG is a non-profit research group based on donated support. The researchers, this centre, and the NCIC CTG will not receive any direct benefit for conducting this study.

CONTACTS

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to your study doctor. Or, you can meet with the doctor who is in charge of the study at this institution. That person is:

_____	_____
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

_____	_____
Name	Telephone

Version date and/or REB approval date of this form: _____

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to my medical records as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree to take part in this study.

_____	_____	_____
Signature of Participant	PRINTED NAME	Date
_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

NCIC CTG Participant Code: _____

Complete the following section only if the participant is unable to read or requires an oral translation:

- The informed consent form was accurately explained to, and apparently understood by, the participant, and
- Informed consent was freely given by the participant

_____	_____	_____
Signature of Impartial Witness/Translator *(If participant were unable to read/required an oral translation)*	PRINTED NAME	Date

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.

***Note to Centres**: When sending a signed copy to the NCIC CTG, the participant's printed name and the bottom half of their written signature, must be blacked out leaving only the upper portion of the signature visible but not identifiable (for verification that a signature was applied).*

Version date and/or REB approval date of this form: _____

SAMPLE -OPTIONAL - Informed Consent Form

A MULTICENTRE RANDOMIZED PHASE II TRIAL COMPARING NAB-PACLITAXEL TO PACLITAXEL IN PATIENTS WITH ADVANCED UROTHELIAL CANCER PROGRESSING ON OR AFTER A PLATINUM CONTAINING REGIMEN

Trial Code: BL.12

Researcher: Dr. _____

Sponsor: NCIC Clinical Trials Group

Le formulaire de consentement est disponible en français sur demande.

Note to centre: If an REB approved French consent is not used at your institution you should remove the above statement.

Tissue and Blood Collection and Banking

Optional tissue banking: The researchers doing this study are interested in doing research studies on tissue samples from your diagnostic cancer specimen to better understand the nature of cancer and how patients respond to treatment. The research that may be done with your tissue may not directly benefit you. It may help people in the future who have the same kind of cancer as you have. If you wish to support such research, you may choose to have your tissue stored at a central tissue bank for use now or in the future. This storage of tissue for future use is called “banking”. The “banking” of this tissue is an optional part of this study. You may refuse to have your tissue banked and still may take part in the main study. If you agree to have the tissue stored for future research, please read and sign this consent form, which deals specifically with tissue banking for future research.

WHAT IS INVOVED IN OPTIONAL TISSUE BANKING?

If you agree to donate your tissue, the samples collected will be from your cancer and some of the normal tissue surrounding your cancer that has already been removed by biopsy or surgery. No further surgeries or biopsies are needed for this purpose.

Any tissue collected will be stored at a central tissue bank (a facility where tissues are stored for future research) located at Queen’s University in Kingston, Ontario. The samples will be kept indefinitely, or until they are returned to the hospital where you had your surgery or biopsy. Tissue will be used for research purposes only and will not be sold. The research done with your tissue may or may not help develop commercial products or tests. There are no plans to provide payment to you if this happens.

Optional blood banking: The researchers doing this study are interested in doing research on blood samples collected at the same time as your routine blood tests. These blood samples may help us understand who will benefit the most from this type of treatment. The banking of these samples is an optional part of this study. You may refuse to have your samples banked and still may participate in the main study.

If you agree to donate your samples, they will be taken at the same time as your study related tests. This means 2 extra 5 ml (1 teaspoon) blood samples will be taken with a needle from a vein in your arm. The needles used to take blood might be uncomfortable. You might get a bruise, or rarely, an infection at the site of the needle puncture.

Any blood samples collected will be stored at a central tissue bank (a facility where tissues, including tumours, blood and urine, are stored for future research) located at Queen's University in Kingston, Ontario. The samples will be kept until they are used up. The samples will be used for research purposes only and will not be sold. The research done with your samples may or may not help develop commercial products or tests. There are no plans to provide payment to you if this happens.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Taking part in the tissue/ blood collection and banking part of this study is voluntary. You may choose not to take part, or may at any time withdraw your consent for this portion of the study and ask that the collected tissue / blood samples not be used. Deciding not to take part, or deciding to withdraw your consent for this portion of the study later, will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating, and no longer want your tissue and/or blood samples to be used in this research, you should tell your doctor. Your doctor will notify the NCIC Clinical Trials Group (NCIC CTG) who will ensure the samples are destroyed (blood) or returned to the hospital where you had your original biopsy or surgery (tissue). If tests have already been done on your sample and included in an analysis or publication, it will not be possible to withdraw these.

All the information provided in the main study consent form about confidentiality, costs, your rights as a participant, and who to contact with questions, applies to this consent form as well.

HOW WILL THE IDENTITY OF MY SAMPLES BE PROTECTED?

The identification that will be on your tissue samples kept in the bank may include your participant code, pathology identification number, initials and tumour bank code. The identification on blood samples may include your participant code and initials. Samples will be given only to researchers whose proposals have been approved by the NCIC Clinical Trials Group and who are bound by a confidentiality agreement. Any research done on your samples will have been approved by a research ethics board. A research ethics board oversees the ethical conduct of a study, including protection of patient rights, confidentiality and safety. Tissue used for research is identified only by a special code to protect your identity and privacy.

Reports about any research done with your samples will not be given to you or your doctor. These reports will not be put in your medical records. The research using your samples will not affect your care.

In the future, people who do research with your sample may need to know more about your health. While the researchers coordinating this study may give them reports about your health, they will not give them your name, address, phone number or any other information that will let them know who you are.

WILL GENETIC TESTING BE DONE ON MY TISSUE SAMPLES?

All cancers are caused by changes in our genes or by changes in when or how these genes are expressed. NCIC CTG does not consider the study of changes in the genetic material of cancer cells to be “genetic research”, as these changes are acquired after you are born and not passed on in families This type of testing may be done on your samples if you agree to allow your samples to be banked for future research.

Some changes in genes that are inherited may determine the way a person will respond to treatment. These changes may also determine what kind of side effects a person will have when they receive different kinds of treatment. These genetic changes do not cause cancer or other diseases and the study of these changes is not considered by the NCIC CTG to be “genetic testing”. This type of testing may be done on your samples if you agree to allow your samples to be banked for future research.

Some cancers are a result of genetic changes that are inherited (passed on in families). Some genes that are inherited may determine a person’s chance of developing a particular disease, including cancer. Studies to look for these inherited genes that may cause cancer or other diseases are considered “genetic testing”. As part of future studies, researchers may want to study the genetic material that is inherited through families and that may cause cancer or other diseases. This type of testing may be done on your samples if you agree to allow your samples to be used for future “genetic testing”.

Participating in “genetic testing” (testing for inherited genes that may cause cancer or other diseases) can involve risks for participants and their families. If you are identified as belonging to a high-risk group for developing a specific disease it could affect employment, health or life insurance, or might alter decisions about having children. This is why “genetic testing” results are not given to you, they are not put into your medical records and every effort is made to protect the privacy and confidentiality of these results. The chance of genetic test results being released in a way that can be linked to you is very small, however you should be aware of the risks. If you do not wish to have your samples used for “genetic testing”, you may indicate your wish at the end of this consent form.

SIGNATURES

☐ I agree to allow tissue samples from my tumour and some of the normal tissue surrounding my tumour to be collected for the purposes described here.
☐ I do not agree to allow tissue samples from my tumour and some of the normal tissue surrounding my tumour to be collected for the purposes described here.

☐ I agree to allow blood samples to be collected for the purposes described here.
☐ I do not agree to allow blood samples to be collected for the purposes described here.

☐ I agree to allow my samples to be used for genetic testing to see if my cancer may be hereditary.
☐ I do not agree to allow my samples to be used for genetic testing to see if my cancer may be hereditary.

PLEASE CHECK THE APPROPRIATE BOXES ABOVE BEFORE SIGNING

_____	_____	_____
Signature of Participant	PRINTED NAME	Date
_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

NCIC CTG Participant Code: _____

Complete the following section only if the participant is unable to read or requires an oral translation:

- The informed consent form was accurately explained to, and apparently understood by, the participant, and
- Informed consent was freely given by the participant

_____	_____	_____
Signature of Impartial Witness/Translator *(If participant were unable to read/required an oral translation)*	PRINTED NAME	Date

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.

***Note to Centres**: When sending a signed copy to the NCIC CTG, the participant's printed name and the bottom half of their written signature, must be blacked out leaving only the upper portion of the signature visible but not identifiable (for verification that a signature was applied).*

Version date and/or REB approval date of this form: _____