



PATIENT INFORMATION AND CONSENT FORM

STUDY TITLE

INVESTIGATOR: Name

CO-INVESTIGATORS: Name(s)

SPONSOR: If applicable

STATEMENT OF RESEARCH

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. You may choose to discuss it with your friends and family.

You are being invited to take part in this study because you _____. The usual treatment for patients like you is _____. Although _____, there is a chance you could _____. It is possible that giving extra treatment with _____ may stop this from happening, but nobody knows for certain if this is the case and which, if any, is the best type of _____ to use. Many people do suffer some side effects from _____.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out whether _____

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About ___ people from _____ will take part in this study.

The study should take _____ to complete and the results should be known in ___ years.

WHAT IS INVOLVED IN THE STUDY?

Please see the diagram attached to the end of this consent form.

Randomization (assignment to a group):

If you decide to participate you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctor can choose what group you will be in. You will have a one in two chance of being placed in any group.

You will / will not be told which treatment you are to get.

Treatment:

Group 1: _____

If you are randomized to Group 1 you will receive

This procedure will take _____. The dose of _____ may be changed if you have side effects.

Group 2: _____

If you are randomized to Group 2 you will receive _____. The dose of the drug may be changed if you have side effects.

Procedures and Medical Tests:

The following tests will be done at the hospital or clinic to make sure that you are eligible for this study. None of these tests are experimental. They are routine.

- physical examination
- chest x-ray
- CT scan of _____
- other imaging tests of your body
- blood tests (3 teaspoons of blood taken)
- physical examination

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

The needles used to take blood or inject substances for body scans might be uncomfortable. You might get a bruise, or rarely, an infection at the site of the needle puncture.

Questionnaires:

You will be asked to fill out a questionnaire every _____ while you are receiving treatment and _____ after treatment has finished. This questionnaire asks about _____ and takes about _____ minutes to complete. It may remind you of unpleasant things about your

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

HOW LONG WILL I BE IN THE STUDY?

Your treatment with _____ will last about _____ if you are randomized to Group 1 or Group 2. The researchers can take you off the study treatment early for reasons such as:

- x
- y
- z
- Your doctor no longer feels this is the best treatment for you.

You can refuse to participate in this study or stop participating at any time and your doctor will continue to treat you with the best means available. If you decide to stop participating in the study, we encourage you to talk to your doctor first.

No matter which group you are randomized to, and even if you stop treatment early, we would like to keep track of your medical condition for _____ to look at the long-term effects of the study treatments.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for the side effects listed below. You should discuss these with your doctor. As with any experimental drugs additional unexpected and sometimes serious side effects are a possibility.

Specify all possible risks associated with participation in the study.

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 uncomfortable. Many side effects go away shortly after chemotherapy is stopped but in some cases side effects can be serious, long-lasting or permanent.

Risks and side effects related to Group 1: _____

Risks and side effects related to:

Very likely:

- A
- B
- C
-

Less likely:

CONFIDENTIAL

- d
- e
- f
- g
-

Rare:

- a
- b

Risks and side effects related to Group 2:

Very likely:

- a
- b
- c
-

Less likely:

- d
- e
- f
-

Reproductive Risks:

Pregnancy and this trial are not compatible. The effects the drugs used in this study may have on a fetus are unknown. Therefore, due to the risk or potential risk to the fetus, women who are pregnant, or planning to become pregnant are therefore excluded from this trial. Women who are breast -feeding are also excluded from this trial. Women and men of childbearing potential are advised to discuss appropriate family planning with their physician if they are interested in enrolling in this trial. Unless you have had a hysterectomy, a tubal ligation, are post-menopausal, or not at risk of pregnancy, you are advised to practice an appropriate method of family planning during the treatment period. If you do become pregnant you must inform your doctor immediately and you will be withdrawn from the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. Your _____ but these things cannot be predicted for you. We hope the information learned from this study will benefit other patients with pancreas cancer in the future.

WHAT OTHER OPTIONS ARE THERE?

If you decide not to participate in this study, your doctor will discuss other treatment options with you. These may include:

- x
- y

- z

You may get study drugs at this centre and other centres even if you do not take part in the study.

Please talk to your doctor about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Your personal information will be kept confidential.

- your name will not be used in any reports about the study
- you will be identified only by a study code, initials, birthdate and hospital/clinic number
- identifying information will be kept behind locked doors

WHAT ABOUT COSTS OR COMPENSATION?

The study drug _____ will be given to you free of charge as long as you receive treatment on the study.

You will receive no compensation for participation in this study.

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 waive any of your legal rights for compensation by signing this form.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. 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. Your doctor will discuss further treatments with you and continue to treat your cancer with the best means available.

You will be given a copy of this signed and dated consent form and an additional copy will be placed in your health record.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about taking part in this study you can talk to your doctor. Or, you can meet with the doctor who is in charge of the study at this institution. That person is:

Dr. _____ at **416 530** _____.

If you would like advice regarding your rights as a study participant, you can talk to someone who is not involved in the study at all. That person is:

Dr. Hazel Markwell (Chair, Research Ethics Board) at 416 530-6750

APPROVAL PROCESS

The Research Ethics Board has reviewed the ethical aspects, physician compensation issues and financial aspects of this study and has approved it.

SIGNATURES

My signature on this consent form means the following:

- The study has been fully explained to me and all of my questions have been answered
- I understand the requirements and the risks of the study
- I authorize access to my medical records as explained in this consent form
- I agree to take part in this study
- I have received a signed copy of this consent form

Name of Participant (Print)

Signature of Participant

Date

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

(Witness may or may not be required, see Consent Form Guidelines.)

Signature of Witness

Date

_____ TRIAL

