

Consent Form for Collection of Tissue Samples in RNAlater Solution at Diagnostic Biopsy

Why have I been asked to take part in this research study?

You are being asked to take part in this research study because your doctor believes you may have rectal cancer. Your doctor will take a small sample of the tumor (a biopsy) in your rectum to determine if it contains cancer cells. We would like to have your doctor place some of this tissue in a special solution called “RNAlater” at the same time that your biopsy is performed. RNAlater preserves genetic material so that it can be examined in a laboratory. The tissue in RNAlater will be sent to a group called the National Surgical Adjuvant Breast and Bowel Project (NSABP). The NSABP is a group of researchers and doctors who are studying cancer.

Your sample collected in RNAlater can be valuable to researchers who are trying to set up the equipment that will look at tumor samples. The researchers may also use your sample to decide the best methods, both new and existing, to evaluate tumor samples. Your sample will be sent to the NSABP with a code number and they will not have any of your personal information (such as your name, age, sex, disease history, etc.) linked with your biopsy sample used for this testing.

It is your decision whether or not to take part in this research study. Please read this entire consent form and take time to make your decision. We encourage you to talk with your doctor, your family, and/or your friends before you decide.

Who is conducting the study?

If you decide to join this study, you will be taking part in a research study being conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP).

Why is this research study being done?

If your tissue is put in RNAlater solution, it will be possible to do special tests with samples of your RNA (genetic material) that can be taken from the tissue samples.

How many people will take part in the study?

We do not know how many people will agree to take part in this study. The number could be several hundred to several thousand patients from different cancer treatment centers.

What is involved in the study?

If you agree, then some of your tumor samples will be put in the RNAlater solution and sent to the NSABP. Your sample will be saved with a code number and no additional information.

How long will I be on the study?

Collection of your tissue in RNAlater will not add any more time to a standard biopsy. Your sample will be kept by the NSABP until it is used up or this study is over and the NSABP destroys it.

What are the risks to me of being in the study?

The biggest risk from being in this study is the accidental release of private information about you. Every effort will be made to ensure this will not happen.

Are there benefits to taking part in this study?

There will not be any direct medical benefit to you from allowing a sample of your biopsy specimen to be collected in RNA later and sent to the NSABP. We hope the information learned from this study will help patients with rectal cancer in the future.

What other treatment options are there?

This study is not a treatment study; therefore, your medical care will be the same if you choose to take part in this study or if you choose not to. If you choose not to take part, your doctor will continue to give you the best care possible.

How will information about me be kept private?

No personal information will be released to the NSABP as part of this study.

What are the costs?

There is no cost to you for the collection and storage of your tissue sample. If you are injured or become ill from taking part in this study, emergency medical treatment is available and will be provided at the usual charge. No funds have been set aside to pay you in case you are injured.

You or your insurance company will be charged for medical care and/or hospitalization.

You will not be paid for taking part in this study. Your tissue sample will only be used for this research study and will not be sold. The research done with your sample may help to develop new products in the future, but you will not get paid.

Do I have to be part of the study?

You are free to choose to take part or not to take part in this research study.

If you have any questions about the study, you will have a chance to talk with one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What are my rights as a study participant?

Even after you agree to take part in this study, you may withdraw at any time. The NSABP will not know any of your information. Your tissue sample will be sent to them with a code and the code number will be written on this consent form.

If you decide you no longer want your tissue sample to be used, you just need to contact your study doctor and let him or her know that you do not want the NSABP to use your tissue and it will no longer be used for this study. Otherwise, the tissue may be kept until it is used up, or this study is over and the NSABP destroys it.

Your decision will not affect your medical treatment or your relationship with those treating you or with this institution. If you withdraw from the study, you will still be offered all available care that suits your needs and medical condition.

Who can I call if I have questions or problems?

For questions about the study or a research-related injury, contact the physician listed on the cover sheet. For questions about your rights as a research participant, call **(Multicare Investigational Review Board at 253-403-3844.**

Where can I get more information about cancer and its treatment?

You can call the Cancer Information Service at 1-800-4-CANCER or visit the National Cancer Institute's Cancer Trials Websites:

- for cancer information go to <http://cancer.gov/cancerinformation>
- for clinical trial information go to <http://cancer.gov/clinicaltrials>
- You can also visit the NSABP Website at <http://www.nsabp.pitt.edu>.

You can also get information at any time from the doctor in charge of your medical care in this study.

You will get a copy of this form.

Signatures

I have been given a copy of this consent form. I have read the consent form or it has been read to me. This information was explained to me and my questions were answered.

I agree to take part in this research study.

Patients name (printed or typed)

Patients Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date