

Kansas City Clinical Oncology Program

Informed Consent Document for Sample Collection at the Time of the Diagnostic Biopsy

Supplemental Consent Form for Tissue Sample Collection for Z1031: A Randomized Phase III Trial Comparing 16 To 18 Weeks Of Neoadjuvant Exemestane (25 mg daily), Letrozole (2.5 mg), Or Anastrozole (1 mg) In Postmenopausal Women With Clinical Stage II And III Estrogen Receptor Positive Breast Cancer

You are being asked to contribute tissue samples because you are having a biopsy to find out if you have breast cancer. The biopsy may show that you have a type of breast cancer that is affected by the levels of hormones in your body.

If you have this type of breast cancer, you may qualify for participation in the Z1031 study. The purpose of the study is to find out which **hormone therapy** is most effective in shrinking breast tumors in postmenopausal women with hormone-dependent breast cancer. We will give you the main study consent form to sign if you do qualify for the study and you would like more information. This consent form is intended only as a supplemental consent form for tissue collection.

Why are these tissue samples being collected?

You are having a biopsy to find out if you have breast cancer. We would like to collect four additional samples of your tumor. The samples would be used for the correlative science portion of the Z1031 treatment study, but only if you qualify for the treatment study. A correlative science study is a related study that is done as part of the main treatment study. If you do not qualify for the study, these tissue samples would be destroyed.

How many people will have tissue collected?

Tissue collection is required for all participants in the Z1031 treatment study, but we do not know how many participants will have tissue collected at the time of their diagnostic biopsy.

What is involved in the tissue collection?

At the time of your biopsy, we would like to collect four additional samples of your tumor.

Can I decide not to have tissue samples collected?

Yes. You do not have to have extra tissue collected. If you do not agree to tissue collection, you will not be able to participate in the treatment study.

What are the risks of tissue collection?

Possible risks related to collecting these tissue specimens include:

- Bleeding at the time the samples are removed.
- Infection at the time the samples are removed.
- Pain at the time the samples are removed.

There may be other risks we cannot predict. For additional information about the risks, please speak with your doctor.

What are the costs of tissue collection?

There are no costs and no payment for tissue collection. Your specimens will be used for research purposes only. They will not be sold. You will not be paid for your specimens even if future research helps to develop new medical products.

Are there benefits to taking part in the tissue collection?

There may not be direct benefit to you. We do know that the information from the treatment study and the correlative science study may help doctors learn more about breast cancer and the best way to treat it. This information could help future cancer patients.

What other choices are there?

You can choose not to provide tissue samples. The choice is up to you. No matter what you decide to do, it will not affect your care.

Will my medical information be kept private?

No medical information about you will be collected unless you qualify for the treatment study. A separate consent form will be provided to you if you qualify for the treatment study and would like more information.

What happens if I am injured because I took part in this tissue collection?

You will get medical treatment if you are injured as a result of taking part in this tissue collection. You and/or your health plan will be charged for this treatment.

What are my rights as a participant?

Taking part in this sample collection is voluntary. Even if you decide now that your specimens can be collected, you can change your mind at any time in the future. Just contact your doctor and let him or her know that you do not want us to use your specimens. Your specimens will be discarded and no longer used for research. Doing so will not result in any penalty or loss of benefits to which you are entitled.

Whom do I call if I have questions or problems?

Contact your doctor NAME(S) at TELEPHONE NUMBER.

You will get a copy of all pages of this consent form.

Signature

I have read the consent form or it has been read to me. This information was explained to me and my questions have been answered to my satisfaction. I voluntarily consent to tissue sample collection.

Patient's Signature _____ **Date** _____