

## Komen Tissue Bank -- Tissue Collection Event

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**Consenter job description:** Your job is to help someone decide whether or not to participate, by explaining what is involved in the trial and the details of the study.

1. Let consenter escort know you are ready for a donor and greet your donor.
2. Ask if they have any questions before you get started.
3. For each donor, you will need a consent packet folder.
4. Confirm eligibility by reviewing and completing the eligibility checklist (yellow sheet) with the donor.  
\*\*\* If a donor is allergic to betadine, notify your area lead who will add 2 Chloraprep swabs to the donors packet\*\*\*
5. Mark the appropriate box for sample to be collected. Usually will be blood and tissue.
6. Read the condensed version of the consent to the donor. (see next page)
7. Verify that the donor has read the Informed Consent and HIPAA and ask, “Do you have any questions”?
8. If the donor has no questions, help them complete the consent by doing the following:
  - Have her answer the question on page 5, “are you willing to be re-contacted”, have them mark the appropriate box, initial and date.
  - Have her answer the question on page 6 regarding “willing to give a digital copy of mammogram”. Mark appropriate box and initial and date and complete the information in regards to the mammogram.
  - **VERY IMPORTANT: SIGN AND DATE, then print name on appropriate lines on page 7** of the consent. Please make sure that this is completed or we will NOT be able to use her sample without her signature and date!
9. **Review the Health Authorization Form (HIPAA) with donor**
  - Explain to her that because she will be providing to the study personal health information she needs to complete this form. Instruct by the following:  
Complete contact information and birthdate at the top of the page.  
Print name on the first line, Sign and Date on second. Please check to make sure that the donor has completed both names and date. IF they do not date the form, we will be unable to use their sample.
9. Make sure there is one barcode still attached to the eligibility checklist and put it back in the plastic folder. Review the consent and HIPAA forms for proper documentation and place them in the plastic folder.
10. Take the donor to the height and weight donor escort and hand them their packet.

### Important Notes-

Donor should leave the Consent area with the following things: Their plastic folder with an eligibility checklist, plastic bag with tubes and barcodes, **completed, signed and dated consent form and HIPAA** along with a completed Media Release Form. **The Surgeon will be the final signatory of the Consent when the donor reaches the exam room.**

If the donor refuses to have only one procedure completed (blood or tissue), make sure to change the box at the top of the page.

If the donor withdraws from the study, please notify the event coordinator prior to the donor leaving the area.

**Condensed version of the Consent** (Please be sure every donor understands these key items.)

**Purpose:**

This study is voluntary. The purpose of the study is to collect and store your blood and tissue sample and medical information. This will allow researchers to study differences between women without breast cancer, and those who have had the disease.

**What is involved?**

We will ask you to complete a medical history questionnaire and provide us with about 2 tablespoons of blood from your vein as well as tissue taken from one of your breasts. You will also be contacted yearly for a medical follow-up. Please understand this is not a diagnostic study.

**What is the benefit?**

There is no direct benefit to you, but we hope that information we learn from this study will benefit breast cancer patients.

**Confidentiality:**

We will keep all your information confidential. However, if you choose we would like your permission to contact you in the future. This would allow us to possibly contact you at a later date if we need additional information or samples. If you agree please check the permission statement on page 6 of the consent.

**Compensation:**

You will not receive compensation for this study.

**Questions or Problems:**

This information can be found on page 5 of the copy of consent that I will give you. (Please show them where the information is on page 5 of the consent)

**What is informed consent?**

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants.

The research team provides an [informed consent document](#) that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.