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. **If donor has not yet watched the "Standardized Informed Consent" presentation, take them to the computers and have them watch the video before meeting with an Informed Consenter.**
3. Ask if they have any questions before you get started.
4. For each donor, you will need a consent packet folder.
5. 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 donor's packet***
6. **If a donor is uncomfortable using an iPad and would prefer to proceed with a paper consent, please notify your area lead that you need a paper consent.** Utilize an available iPad for the for the following forms in REDCap:
   a. Media Release
   b. Informed Consent Statement
      i. Enter the appropriate barcode from the Eligibility Checklist on the first screen
      ii. The donor will be guided through the informed consent and periodically prompted to pause and ask questions if necessary.
      iii. As the consenter, ***you will now sign and date*** the consent form as the **"Person Obtaining Consent"** after the donors has signed the last page.
   c. Health Authorization Form (HIPAA)
7. Verify that the donor has read the Informed Consent and HIPAA and ask, "Do you have any questions"?
8. **Second copy of HIPAA Form –** This copy is for the donor. They may have a copy sent to them electronically after completing the REDCap survey **OR** they may request to fill it out on paper. Paper copies will be located at the Consent table.
9. Make sure there is one barcode still attached to the eligibility checklist and put it back in the plastic folder.
10. Take the donor to consent checking and hand them their packet. A donor escort will then take them to Height and Weight.

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 HIPAA** along with completed Media Release Form(s). The second copy of the HIPAA form (without the barcode sticker) can be given to the donor immediately for her records.

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 to complete a brief 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. You will not receive any results about your samples at any time.

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.

Compensation:

You will not receive compensation for this study.

Questions or Problems:

This information can be found on page 8 of the copy of consent that you will receive in their gift bag.

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.