Title: Facilitating Informed Decisions for Contralateral Prophylactic Mastectomy

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RUTGERS Cancer Institute of New Jersey

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# CONSENT TO TAKE PART IN A RESEARCH STUDY
## Cancer Institute of New Jersey

**Title of Study:** **Facilitating Informed Decisions for Contralateral Prophylactic Mastectomy**

**Study Phase 2**

**Principal Investigator:** **Sharon Manne, Ph.D.**
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This consent form is part of an informed consent process for a research study and it will give information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor (the principal investigator) or another member of the study team (an investigator) will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

**Why is this study being done?**
The purpose of this study is to find out if a decisional aid is helpful to women when considering whether or not to have contralateral prophylactic mastectomy. You are free to decide not to take part in the study. Your decision whether or not to take part in the study will not affect your medical treatment at Rutgers Cancer Institute of New Jersey (CINJ).

**Why have you been asked to take part in this study?**

You are being asked to take part in this research study because you have received a diagnosis of Stage 0, 1, 2, or 3a breast cancer or Stage 1-3b who is downstaged to Stage1-3a with neo-adjuvant chemotherapy and are:

A. Scheduled for a surgical consult with breast cancer surgeon at CINJ.
B. Considering Contralateral Prophylactic Mastectomy (CPM), regardless of the surgical treatment of your primary breast cancer (lumpectomy/mastectomy).
C. You are 18 years or above
D. You Speak and read English
E. You do not have hereditary breast/ovarian cancer syndrome (BRCA carrier, strong family history).
F. You have internet access at home

You are able to provide meaningful informed consent.

The study doctor and/or research team may also ask you other questions about your medical history in order to make sure you qualify to be in this study.

**How long will the study take and how many subjects will participate?**

Approximately 130 women from Rutgers Cancer Institute of New Jersey (R CINJ), Memorial Sloan Kettering Cancer Center (MSKCC) and Massachusetts General Hospital (MGH) with primary breast cancer will take part in this phase of the research study.

**What will you be asked to do if you take part in this research study?**

We are asking you to fill out questionnaires for this research study. These questionnaires will tell us about your knowledge, attitude, and mood surrounding Contralateral Prophylactic Mastectomy (CPM). The first survey will take you approximately 15-20 minutes to complete.

There will be a follow-up questionnaire given to you at the time of your post-operative appointment that will ask the same questions as the initial questionnaire and whether or not you have decided to have CPM.

There will also be a follow-up questionnaire six months after the first questionnaire. This questionnaire will ask some of the same questions as the initial questionnaire, but will also ask questions about how satisfied you are with whatever decision you made.

The follow-up surveys will take approximately 20 minutes to complete.

You do not have to answer any questions that make you uneasy. Whether or not you answer any question will not affect your medical care. We will keep the paper copies of the questionnaires in a locked file to protect your privacy.

In addition to the questionnaires you will be completing, the study investigator will collect medical information from your medical chart during the study. This information includes the type and dates of medical treatment that you get.

If you agree to take part in this research study, you will be randomly assigned to a condition.

Condition 1: In this condition you will be provided with the standard medical care available to patients considering CPM. You will receive information from your medical oncologist about CPM.

Condition 2: In this condition, you will be provided with a website address for using the CPM Decisional Aid, a secure username & password emailed to you, and instructions for using the website for the decisional aid. If you are assigned to Condition #2, we will ask you to evaluate and provide feedback on the Decision Support site. Feedback will be collected at the time of the first follow-up survey, but we may also contact you by phone for a short debriefing on your experience with the site.

**What are the risks and/or discomforts you might experience if you take part in this study?**
This study involves research that presents very little risk. There are no physical risks/side effects involved in your taking part in this study. It is possible that you may feel upset by viewing information about contralateral prophylactic mastectomy. During the feedback portion, you do not have to answer any question that does make you upset. Should you become more distressed, please let the coordinator know. An investigator who is trained in clinical psychology and works with cancer patients and their family members is available to give you support, and, if needed, information about other sources of professional help.

An unlikely risk is the potential for the loss/breach of confidentiality. Safeguards are put into place to protect the information you provide to the research team.

You can also discuss the risks and side effects with your doctor.

No guarantee is being offered that you will benefit from this study. While there may not be direct benefit to you, you will provide useful information that may be helpful in improving the care of women with breast cancer.

**What are your alternatives if you don't want to take part in this study?**
Talk to your doctor about your choices before you decide if you will take part in this study. You are under no obligation to take part in this research study. If you decide that you do not wish to take part in this study, you are free to leave the study at any time.

Whether or not you take part in this study will not affect the availability of any other treatment for you. If you choose to take part in this study, you are still free to seek out any other forms of care in which you may be interested.

**How will you know if new information is learned that may affect whether you are willing to stay in this research study?**
During the course of the study, you will be updated about any new information that may affect whether you are willing to go on taking part in the study. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

**Will there be any cost to you to take part in this study?**
There are no costs associated with participation in this study.

**Will you be paid to take part in this study?**
You will receive $25 for each survey you complete. If you complete all 3 surveys (baseline, Follow-up#1 and Follow-up#2) you will receive a total of $75.

**How will information about you be kept private or confidential?**
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The feedback you provide after viewing the decision aid may be audiotaped. The tapes are for the purpose of being able to go back and listen to the valuable feedback you provide, and also to share with other members of the study team who are helping to design the decision aid. Only members of the study team will have access to the audio recordings.

**Who can you call if you have any questions?**
If you have any questions about taking part in this study you can call the study doctor:

Sharon L. Manne, Ph.D.
The Rutgers Cancer Institute of New Jersey
(732) 235-6975

Laurie Kirstein
Memorial Sloan Kettering Cancer Center
(646)-888-5403

If you have any questions about your rights as a research subject, you can call:
IRB Director
(732)-235-9806

**What are your rights if you decide to take part in this research study?**
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

**Authorization to use your health information for research purposes**
Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization

form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

**Do you have to sign this authorization form?**
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

**If you sign, can you revoke your authorization or withdraw your information later?**
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. You may wish to revoke your authorization for the research use or disclosure of your health information in this study, by contacting Sharon L. Manne, Ph.D. in writing.

**What personal information will be used or disclosed?**
Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, information in your medical record such as certain information indicating or relating to a particular medical condition, blood and other tissue samples and related records, physical examinations, x-rays, MRI's, etc. Your personal identity, that is your name, address, and other identifiers, will be kept confidential. You will have a code number and your actual name will not be used. Only your study doctor will be able to link the code number to your name.

Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential. The exception to this rule will be when there is a court order or when a law exists requiring the study doctor to report communicable diseases. In this case, you will be informed of the intent to disclose this information to the state agency. Such a law exists in New Jersey for diseases such as cancer, infectious diseases such as hepatitis, HIV, viruses and many others.

**Who may use or disclose the information?**
The following parties are authorized to use and/ or disclosed your health information in connection with this research study:

- Rutgers University Institutional Review Board (IRB-a committee that reviews research studies to protect people participating in research.)
- Rutgers, the State University of New Jersey (Rutgers)
- Rutgers Robert Wood Johnson University Hospital (RWJUH)
- Rutgers Cancer Institute of New Jersey (CINJ)
- Memorial Sloan Kettering Cancer Center (MSKCC)
- Massachusetts General Hospital (MGH)
- ITX Corps

- DatStat, a company whose software is being used in the study

**Who may receive/use the information?**
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services
- The National Cancer Institute (NCI)

Your information may be re-disclosed (shared) by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will your authorization expire?**
Your authorization for the use and/or disclosure of your health information will never expire.

**Will access to your medical record be limited during the study?**
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

**Where can you get more information?**
You may call the National Cancer Institute's Cancer Information Service at:
Voice: 1-800-4-CANCER (1-800-422-6237) TTY: 1-800-332-8615

For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at: http://cancer.gov/clinicaltrials/understanding/insurance-coverage

You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

If you do not have access to a personal computer, you may access these websites and other information at a computer in the Cancer Institute's Resource and Learning Center on the second floor at no cost to you.

**AGREEMENT TO PARTICIPATE**
You have read this entire form, or it has been read to you, and you believe that you understand what has been discussed. All of your questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____

Date:_____

**Signature of Investigator/Individual Obtaining Consent:**
To the best of your ability, you have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____

**Optional Study Activity for participants assigned to the Decision Aid arm only.**

You are being asked to participate in an optional study activity. If you decide not to participate in the optional study activity, you can still participate in the main research study. Please take your time to make your decision and discuss it with others and your primary care physician.

Your participation in the optional research study activity is voluntary, and you will not be penalized or lose any benefits if you refuse to participate or decide to stop.

After you have completed participation in the main research study, you will have the option to attend a debriefing feedback telephone call with the Principle Investigator from Rutgers Cancer Institute of New Jersey, Dr. Sharon Manne. The purpose of the 15-20 minute call is to collect feedback on the B-Sure Decision Aid website and to discuss your treatment decision-making process. You will not receive additional compensation for attending the call. Again, this telephone feedback interview is completely optional.

Please indicate whether or not you want to take part in this optional research study.

☐ Not applicable

☐ Yes _____SIGNNATURE _____Date_____

☐ No _____ SIGNATURE _____Date_____