



Dear Friend:

Thank you for your interest in participating in the Yoga Study!

To see if you are eligible for the Yoga Study, we would like you to fill out and return the 3 enclosed forms:

- **Yoga Study interest survey.** Please fill out the survey.
- **Consent to review medical records for eligibility screening.** Please read and sign.
- **Authorization to Use and Disclose Protected Health Information for Research.** Please fill in the name and contact information for your health care provider(s), the date of your first mammogram when your breast cancer was discovered, and the date of your last test or procedure for your breast cancer, review and sign.

Please return all three forms to us at the following address.

**Katie Fraser, Yoga Study, MD-B306
Fred Hutchinson Cancer Research Center
1100 Fairview Ave N
Seattle, WA 98109**

Study staff will contact women who are eligible for the study. All information will be kept confidential. If you have any questions about the forms in this packet, please call me collect at (206) 667-6185 or email me at kfraser@fhcrc.org.

Sincerely,

Katie Fraser
Program Assistant
Yoga Study

The Yoga Study

CONSENT TO REVIEW MEDICAL RECORDS FOR ELIGIBILITY SCREENING

THE FRED HUTCHINSON CANCER RESEARCH CENTER

Investigators/Researchers:

- Anne McTiernan, MD, PhD, Principal Investigator, Phone: (206) 667-7979
- Alyson Littman, PhD, Co-Investigator, Phone: (206) 277-4182
- Cornelia Ulrich, PhD, Co-Investigator, Phone: (206) 667-7617
- Rachel Ceballos, PhD, Co-Investigator, Phone: (206) 667-7806
- Bonnie McGregor, PhD, Co-Investigator, Phone: (206) 667-7924
- Jaya Ramapasand, PhD, Co-Investigator, Phone: (206) 221-3550
- Lisa Cadmus, PhD, Co-Investigator, Phone (206) 667-2769

Study staff:

- Katie Fraser, Program Assistant, Fred Hutchinson Cancer Research Center, MD-B306, 1100 Fairview Avenue N., Seattle, WA 98109-1024, Phone: (206) 667-6185
- Claudia Kumai, PA, Physician Assistant, Fred Hutchinson Cancer Research Center, MD-B306, 1100 Fairview Avenue N., Seattle, WA 98109-1024, Phone: (206) 667-2831

Thank you for your interest in this research study. The Yoga Study tests the effectiveness of a yoga program on weight loss, quality of life, and fatigue. Since you are a breast cancer survivor between the ages of 21 and 75, you may be eligible for The Yoga Study.

As part of *screening* to see if you are eligible, we would like to look at your medical records to get information about your breast cancer diagnosis and treatment. We will ask you to sign this consent form and an "Authorization to Use and Disclose Protected Health Information for Research". Screening does not benefit volunteers directly (although we hope the study will help us learn about the potential benefits of yoga for breast cancer survivors).

You do not have to let us look at your medical records. You are free to say yes or no, or to withdraw your consent later. If you say no, we cannot enroll you in The Yoga Study. But there is no penalty or other loss of benefits. Whatever you decide, your regular medical care will not change.

The risks of screening are minimal. There is a small risk that information about your cancer diagnosis and treatment may be released by accident. For some people this may lead to problems with family members or insurance. This risk is very low, because we keep your personal information confidential. Study records are stored in a locked file room that is accessible only to study staff. All study staff members and investigators have signed a confidentiality pledge.

Some organizations may need to look at your records for research, quality assurance, or data analysis. These include the Hutchinson Center, its institutional review board (a group that reviews the study to protect your rights), and the US National Institutes of Health, National Cancer Institute, Office of Human Research Protections, and other agencies as required. Also, your personal information may be given out if required by law.

If you have questions or concerns about The Yoga Study or its screening procedures, please call Katie Fraser at (206) 667-6185. If you have questions about your rights as a research participant, call Karen Hansen in the Hutchinson Center's Institutional Review Office at (206) 667-4867.

If you have read this form (or had it read to you), asked any questions, and agree to the examination of your medical records as part of eligibility screening for The Yoga Study, please sign:

Participant / date

The Yoga Study

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

THE FRED HUTCHINSON CANCER RESEARCH CENTER

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I authorize: _____

Name of Healthcare Provider/Institution	Full Address/Phone

to provide copies of my medical records as specified below to:

The Yoga Study, Fred Hutchinson Cancer Research Center
1100 Fairview Avenue N., MD-B306, Seattle, WA 98109
Phone: (206) 667-7866; Fax: (206) 667-6721

Type of Record Requested

Please note: Your breast cancer diagnosis and treatment will dictate which type of medical records you have for your breast cancer. We will need to request the records described below:

- Pathology Report
- Discharge Summary
- Operative or Procedure Report
- Mammogram film
- Radiology Consult
- Physicians Attestation
- Tumor Registry Abstract Form
- Mammogram report
- Radiology Scan
- MRI Report
- Oncology Consult

Reports are requested for procedures or hospitalization:

From (Date of first mammogram where your breast cancer was discovered): ____/____/____

To (Date of your last test or procedure for your breast cancer): ____/____/____

The Yoga Study

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

By signing, you authorize Fred Hutchinson Cancer Research Center (FHCRC) and their staff of researchers to use and disclose protected health information (PHI) that identifies you. They will use your PHI to screen for eligibility in the Yoga Study. The Yoga Study tests the effectiveness of a yoga program on weight loss, quality of life, and fatigue.

You do not have to sign this authorization.

If you sign and then change your mind, you may revoke your authorization anytime. Write to Katie Fraser, the Program Assistant, at the address on page one. If you revoke your authorization, you may no longer participate in the Yoga Study.

By signing this authorization, you also acknowledge the following:

- If you revoke this authorization, the Researchers may still use, create and PHI they have already obtained. They would use it to maintain the reliability of their research.
- After the researchers have obtained your PHI, the privacy protections in The Health Insurance Portability and Accountability Act (HIPAA) no longer apply. Other federal and state privacy protections will still apply.
- No publication about the research will reveal your identity unless you give written permission.
- Your PHI will be kept in a database or data repository until the study ends.
- This authorization will expire at the end of the study, unless you revoke it.
- The researchers may share your PHI with certain people and groups as required or permitted by law. These include the Fred Hutchinson Cancer Research Center, its Institutional Review Board, and the US National Cancer Institute, Office of Human Research Protections, and other regulatory authorities.
- The researchers may use and share your PHI for other research. They will remove any information that could identify you.
- These limitations continue even if you revoke this authorization.

Please retain the second copy of this release form, as it is yours to keep.

Signature of participant or participant's Legal Representative

Date

_____-_____-_____
Social Security Number (Optional)

_____-_____-_____
Date of Birth (required)

Printed name of participant or participant's
Legal Representative

Representative's relationship
to participant

The Yoga Study

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