STOCKTON UNIVERSITY

School of Social and Behavioral Sciences
P: 609.652.4512 • F: 609.626.5559

101 Vera King Farris Drive | Galloway NJ 08205 9411
stockton.edu

Stockton University
& Atlanticare Regional Medical Center (ARMC) Consent Form

Commented [ML1]: All Informed Consent Forms (ICF) should be on Stockton letterhead or letterhead of the lead agency.

Impact of Yoga on Chemotherapy in Women with Breast Cancer

Why am I being asked to volunteer?

You are being invited to participate in a research study. You are being asked to volunteer since you meet the requirements for enrollment into this study. Your participation is voluntary which means you can choose whether or not you want to participate. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

Purpose: The purpose of this study is to determine the effects of Yoga on the quality of life in women undergoing adjuvant chemotherapy for breast cancer. The specific areas of quality of life that will be assessed include: perceived cognitive function, fatigue pain and spirituality, as well changes in flexibility and balance. The results of this study will hopefully lead to a way of treating some of the common negative side-effects that affect women undergoing chemotherapy for breast cancer. To be included in this study, you must meet the following criteria:

Commented [ML2]: The ICF should give a little description about the research. If the researcher is concerned about biasing the results, the information here can be limited as long as there is a separate debriefing form given to the participant at the end of the study.

- A diagnosis of breast cancer in Stage I, II, or III, with no prior cancer diagnoses.
- Plan to have treatment with chemotherapy with or without radiotherapy under the direction of an ARMC physician.
- Age 18 years or older.
- Able to understand and complete all questionnaires in English or Spanish.
- Must be able to understand and give written informed consent.

Procedures: After you agree to take part in the study, a short medical history will be taken including information such as your current medications and past surgeries. If you meet all requirements, you will be assigned to one of two groups. One group will receive a 1 hour yoga session, led by a trained instructor, twice per week, for 6 weeks and once per week for the remaining 6 weeks of chemotherapy. This will be provided by XXXXX Studio and a certified instructor in yoga. The second group will be asked to carry out normal activities of daily living. You will be asked to fill out questionnaires and be tested for flexibility and balance at the beginning of the study, at 6 weeks and 12 weeks and upon completion of the study at 1 and 3 months. At the end of the study, both groups will be able to participate in yoga classes.

Commented [ML3]: The ICF must explain the amount of time and activities that are to be performed during the study.

Risk: There is minimal risk involved in this study. A certified yoga instructor will give directions on the correct way to perform the exercises. Modifications will be provided throughout each session when needed. You may feel some muscle soreness from the various postures performed in yoga.

Commented [ML4]: ICF must discuss risk. If there is no risk, you state that. If there is risk you must discuss why and what the risk involves and give the participants contact information for services that can be utilized if harm occurs after participation.

Benefits: You will learn a potentially new, non-invasive, way to manage some of the negative side-effects associated with chemotherapy. Upon completion of the study, if you are in the group that did not perform yoga, you will be offered complementary classes at XXXXX in XXXXXX.

Commented [ML5]: Any benefits/compensation that the participant will receive must be noted. If there is none, it must state that.

Alternatives: Your alternative is not to participate in this study and to continue usual care as recommended by your doctor.

Commented [ML6]: If alternative treatments are available, the participant must be aware.

Costs: None. There is no registration or participation fee. All participants will have to provide their own transportation to Atlanticare Regional Medical Center for baseline measurements, and again at 6 and 12 weeks during chemotherapy and 1 and 3 months after the start of the study. The yoga group will be required to provide their own transportation to XXXXX Studio for 12 weeks. Various sites are established in the region to best meet the needs of travel time for the classes

Who can see or use my information? How will my personal information be protected?

Commented [ML7]: The ICF must discuss who will have access to the data. See # 1-5, below, for explicit detail.

Your privacy and the protection of your health information are important to us. This section of the consent will cover:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information
- All data obtained from CogState™ testing will be returned to CogState™ for analysis. (CogState™ is a simple, valid and reliable computer based test used to determine an individual's memory, attention and decision making ability. It has been designed to be used in research and clinical trials where sensitive monitoring of changes is required.)

1. Personal health information about you that will be collected in this study

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study:

- Name
- Address
- Telephone number
- Current and past medications or therapies
- Information from the tests and procedures described earlier in this document

2. Who will use your information within the institution?

Your personal contact information is important for Atlanticare Regional Medical Center (ARMC) and Richard Stockton College of New Jersey (RSC) study team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care.

However, to further protect your privacy on any records and information disclosed outside of ARMC and RSC, you will be identified only by a unique code number for this study. Only the Principal Investigator or his designate will have access to the key. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

3. The personnel who may use or disclose your personal health information

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team
- The ARMC and RSC Institutional Review Boards (the committees charged with overseeing research on human subjects)

4. How long will ARMC and RSC be able to use or disclose your personal health information?

Commented [ML8]: ICF must state where the data will be stored and for how long.

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, ARMC and RSC may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given

written permission for the Principal Investigator to do so. However, ARMC and RSC Investigational Review Boards may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care will not be included in your medical record.

Commented [ML9]: ICF must state if the research is confidential or anonymous and how the researcher will protect the data.

5. Access to your records

You will be able to request access to your medical record when the study is completed. During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Changing your mind

Commented [ML10]: The ICF should reinforce/remind the participant that s/he can withdraw without penalty.

You may withdraw from the study for any reason simply by explaining this to the Principal Investigator or a member of the study team. If you decide not to participate, you are free to leave the study at anytime. Withdrawing will not interfere with your future care.

You may also withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

Who can I call about my rights as a research participant:

Commented [ML11]: Researchers must provide contact information to the participants so that they may inquire about the study after it is complete. Email and phone should be given in case the participant does not have access to one. If a student is conducting the research, his/her name can be on the ICF, but the faculty sponsor should also provide information.

If you have questions regarding your participation in this research study or if you have any questions about your rights as a research subject don't hesitate to speak with the Principal Investigators, Dr. XXXXX at (609) XXX-XXXX or Dr. XXXXXX (609) XXX-XXXX . Concerning your rights as a research subject, you may also contact the Investigational Review Board at ARMC by calling (609) XXX-XXXX.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting ARMC and RSC to use your personal health information collected about you for research purposes within our institutions.

Questions: If you have further questions feel free to call XXXXXXXXXX, the research coordinator at (888) XXX-XXXX.

Conclusion: By signing below you agree that:

- You are taking part in this study freely
- You have been told the reason for this study
- All of your questions have been answered
- You have read this form or someone has read it to you
- You will answer all questions honestly
- You agree to comply to the rules of this study
- You will not make additions to your existing daily exercise and activities

I have read this consent form and understand all of the above.

Signature of Participant:_____ **Date:** _____

Commented [ML12]: Participants must sign one copy and be given one to take with them so that they have all information after they leave.

Signature of Witness: _____ **Date:** _____

Commented [ML13]: Upon IRB approval, the ICF will be stamped with the approval end date (one year after IRB approval was granted). The researcher will copy the stamped ICF and use that copy for research purposes. At the end of the year, a renewal must be filed if data collection is not complete.