Informed Consent to Participate in Research

The University of Texas at Austin

You are being asked to participate in a research study. This form provides you with information about the study. The Principal Investigator (the person in charge of this research) or his/her representative will also describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don’t understand before deciding whether or not to take part. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled.

Title of Research Study:


Principal Investigator(s) (include faculty sponsor), UT affiliation, and Telephone Number(s):

PRINCIPAL INVESTIGATOR:
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GRADUATE STUDENT INVESTIGATOR:
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CO-INVESTIGATOR #1:
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No current financial support

What is the purpose of this study?

The objective of this study is to characterize the mechanical properties of the breasts and upper abdomen skin of 50-75 healthy volunteers, ranging in ages 18–65 years and meeting the required inclusion and exclusion criteria. The upper abdomen is also being tested because its very often donor tissue for breast reconstruction.

The study’s results will aid in the development a 3D computer model of the female breast that is necessary for computer-assisted breast reconstruction in women with breast cancer.

What will be done if you take part in this research study?

Estimated volunteer time required: 1-2 hours; conducted by female researcher(s).

1) You will be asked to complete the “Volunteer Demographic and Medical History Questionnaire.”

2) The researcher will briefly review the completed questionnaire with you to confirm your eligibility for inclusion in the study.

3) Once you have completed the “Informed Consent to Participate in Research” form and “Volunteer Demographic and Medical History Questionnaire,” you will be assigned a unique volunteer number (VN) that will be stamped onto your copy of the “Informed Consent to Participate in Research” form. (If you should later decide to withdraw from the study, the VN will be the only link to your medical history and data records.)

4) The researcher will briefly demonstrate the functioning of the experimental device used to measure your skin/tissue properties.

5) The researcher will then give you a hospital gown and ask you to disrobe “from the waist up” for the frontal chest and upper abdomen examination. (A privacy
screen will be provided during the disrobing process.) You will be asked to remove any deodorants, lotions, etc. from the examination area that may interfere with the proper attachment of the measurement device. You will be provided a pre-moistened, alcohol wipes for this purpose.

6) You will be asked to stand erect (face outward) against a plain vertical surface while the researcher measures and records for each breast:
   a) sternal length, i.e. distance from the sternal notch to the nipple;
   b) distance from the nipple to the inframammary fold;
   c) distance from the nipple to the body centerline.

7) You will be asked to stand erect against a plain vertical surface while the researcher takes digital photographs of your chest, neck to stomach:
   a) frontal view;
   b) left side view;
   c) right side view.
You will be asked to confirm that no personally identifying features are captured in the digital images.

8) You will be asked to lie down (face up) on a flat surface during the entire skin/tissue measurement process.

9) The researcher will mechanically test up to 24 regions (with up to 3 repetitions) on each breast and up to 4 regions (with up to 3 repetitions) on your upper abdomen, explaining what is happening at each major step.

   It is not anticipated that you experience any substantial discomfort during the testing. However, if you do, you should immediately alert the researcher to any discomfort and/or concerns you have during the testing so that she can make appropriate adjustment(s).

10) At this stage, the data collection will be complete and you will be free to redress and ask any questions you might have regarding the study, and/or procedures.

**What are the possible discomforts and risks?**

Biomechanical assessment, are non-therapeutic, non-invasive assessments without known harmful effects. However, there may be risks that are unknown at this time.

The suction created by the experimental may cause a feeling being touched lightly on the skin. The probe may leave residual “ring” marks. However, all known marks have lasted less than 15 minutes and leave no known permanent damage.

Women who are allergic or have a history of being sensitive to adhesive medical tape may want to consider not participating in this study. In addition, women who have any existing skin/tissue damage or skin disorders will be excluded from study.
In addition to the possible physical risks given, this study may involve potential psychological and/or emotional risk from participation.

While this research study may involve unpredictable physical and psychological risks to the participants, no treatment will be provided for research related injury and no payment can be provided in the event of a medical problem.

If you wish to discuss the information above or any other risks you may experience, you may ask questions now or call the Principal Investigator listed on the front page of this form.

**What are the possible benefits to you or to others?**

No direct benefit is foreseen for study participants. The indirect benefits are the participation and support of breast health and reconstruction research.

**If you choose to take part in this study, will it cost you anything?**

No

**Will you receive compensation for your participation in this study?**

No

**What if you are injured because of the study?**

No medical treatment will be provided or available in case of injury as a result of participation in this study. No payment can be provided in the event of a medical problem.

**If you do not want to take part in this study, what other options are available to you?**

Participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence current or future relationships with The University of Texas at Austin.

**How can you withdraw from this research study and who should I call if I have questions?**

If you wish to stop your participation in this research study for any reason, you should contact: Professor Tess Moon at (512) 471-0094 with your volunteer number (at the top of the front page of this form).
You are free to withdraw your consent and stop participation in this research study any time during the data collection phase when your records are retrievable via your VN. Moreover, your withdrawal of consent will be without penalty or loss of benefits for which you may be entitled. Throughout the study, the researchers will notify you of new information that may become available and that might affect your decision to remain in the study.

In addition, if you have questions about your rights as a research participant, please contact Clarke A. Burnham, Ph.D., Chair, The University of Texas at Austin Institutional Review Board for the Protection of Human Subjects, (512) 232-4383.

How will your privacy and the confidentiality of your research records be protected?

The health information you provide and we collect will referenced only by your volunteer number (VN). In addition, the study records do not contain any information that identifies you or could be used to identify you as an individual.

Authorized persons from The University of Texas at Austin and the Institutional Review Board have the legal right to review your research records and will protect the confidentiality of those records to the extent permitted by law. If the research project is sponsored then the sponsors also have the legal right to review your research records. Otherwise, your research records will not be released without your consent unless required by law or a court order.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Will the researchers benefit from your participation in this study [beyond publishing or presenting the results]?

No
Signatures:

As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

Signature and printed name of person obtaining consent  Date

You have been informed about this study’s purpose, procedures, possible benefits and risks, and you have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

Printed Name of Subject  Date

Signature of Subject  Date

Signature of Principal Investigator  Date