EFFECTIVE

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MCW IRB

Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

Assessing Breast Cancer Risk Prior to Gender-Affirming Chest Masculinization Surgery

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Definitions

Chest Masculinization Surgery – often called “top surgery” – is a surgical procedure in which most of the breast tissue is removed to give the chest a more masculine appearance

Risk Reducing mastectomies – a surgical procedure that aims to remove all breast tissue to reduce the change that breast cancer can develop in the future.

Purpose

This project is being done to determine if certain individuals undergoing chest masculinization surgery should consider risk-reducing mastectomies as part of their operation based on their estimated breast cancer risk.

Length

- You will be in this research project for about 30 minutes.. Research activities will occur for 1 year.
- We would also like to follow you for about 1 year after enrollment.

Activities

List of visits:

- Initial Breast Cancer Risk Assessment – phone or virtual (all study participants)
  - Total Number: 1
  - Total Time: 30 min

Activities that will occur at various visits:

Invasive Activities

- None

Non-invasive Activities

- Lifetime breast cancer risk assessments using the Gail and IBIS Models.

Risks

This is a brief list of the most commonly seen risks. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

- Stress and/or anxiety related to undergoing a personalized breast cancer risk assessment

Benefits

This project may or may not help you, but we hope the information from this project will help us provide better health services for individuals undergoing chest masculinization surgery.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Chandler Cortina, MD, at 414-955-1453

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you were assigned female or intersex at birth, identify as non-cisgender, and are considering undergoing chest masculinization (top) surgery.

A total of about 35 people are expected to participate in this research from the Medical College of Wisconsin and Froedtert Hospital.

The Director of the project is Chandler S Cortina, MD, MS in the Department of Surgery. A research team works with Dr. Chandler Cortina. You can ask who these people are.

The research team will be paid by the Sponsor, Advancing a Healthier Wisconsin for carrying out this project.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you do not agree to join, or if you leave, you will not be penalized or lose any benefits that you had before starting the research project. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to determine the percentage of non-cisgender persons who have an elevated lifetime breast cancer risk who are thinking about undergoing top surgery, measure the percentage who can consider risk reducing mastectomies as part of their top surgery, and compare a person's estimated lifetime risk with their calculated risk and help us to understand how to minimize breast cancer risk for other individuals undergoing top surgery in the future.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

If you agree to participate in this project, you will be scheduled a 30-minute visit, via phone or WebEx, to meet with Dr. Chandler Cortina or Anna Purdy, APNP, to undergo a personalized breast cancer risk assessment and review your medical record.

For this project, the research team will assign you a unique code, such as a series of numbers and/or letters. When sending your project data to our statistical team and Advancing a Healthier Wisconsin, the research doctor will use your unique code instead of other information that could easily identify you.

The data that is recorded with your unique code rather than your name is called "key-coded data". The research doctor will keep a confidential list linking your name to your code and only the research doctor and authorized research team members will have access to this list.

Some study data will identify you (such as medical records), and the ways this data may be used and shared is described later in this form.

PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this project.

_____ Yes, I want the research doctor to inform my primary care physician / specialist of my participation in this project.

_____ No, I do not want the research doctor to inform my primary care physician / specialist of my participation in this project. Please note, this may not be possible depending upon the information placed in your electronic medical record as part of the project.

_____ I do not have a primary care physician / specialist.

We are requesting your email address so we can stay in touch with you throughout the project. This may include setting up clinic visits, sending project-related reminders, or answering any general questions you may have. Email is generally not a secure way to communicate about your health because there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Chandler Cortina, MD, MS at 414-955-1453. You do not have to provide your email address to participate in this project.

B2. HOW LONG WILL I BE IN THE PROJECT?

⇒ The breast cancer risk assessment is expected to take about 30 minutes.
⇒ After your visit is finished, we will follow your electronic medical record for up to 1 year to assess if you underwent top surgery.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

The research doctor may stop your participation in the project at any time for any reason without your consent. He will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems such as distress or anxiety. **You need to tell the research doctor or a member of the research team immediately if you experience any problems or become too upset.**
Risk Assessment/Questionnaire. You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it, or you may stop immediately. If you become upset, please let us know and we can give you information about individuals who may be able to help you.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. If you have questions, you can talk to the project director about whether this could apply to you.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

⇒ This project may or may not help you, but we hope the information from this project will help us develop a better way to counsel individuals seeking top surgery.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs associated with the breast cancer risk assessment. You will be provided with your assessment results. Any clinical visits or procedures that take place outside of the research assessment will be billed to you or your insurance.

If you have questions regarding costs, please contact Dr. Chandler Cortina.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

⇒ You will be paid $100 for participating in the project by undergoing a personalized breast cancer risk assessment. To pay you, we need your social security number. Any payment may be reportable as income on your taxes.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no.
⇒ Whether or not you join this project, you are free to seek services from this or other agencies.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

⇒ After the project has been completed, we will notify you of the results.

When research data are collected and analyzed , there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research data. The results of your research data be placed in your medical record.

The results from the data we collect in this research study are the same quality as what you would receive as part of your health care. The data will be reviewed by a physician who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

The findings of this study will also be presented in an open forum in which results will be discussed with research and community members. You will also be invited to attend this event. The study results presented will be de-identified and will not identify any participants.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Dr. Chandler Cortina, 414-955-1453.

Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Chandler Cortina at 414-955-1453
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); Versiti, Inc.; Children's Wisconsin (CW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital; Froedtert West Bend Hospital; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information we will collect and use for this project is:

- ⇨ Health information collected during this project, such as, questionnaires, your personal gynecological and breast history, and your family history.
- ⇨ Your history of gender-affirming therapy and if you undergo top surgery.

E2. Who will see the health information collected for this project?

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

We may record your research information, including results of tests, procedures or questionnaires done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Chandler Cortina at *8701 Watertown Plank Rd, Milwaukee, WI*. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

E6. Access to records

You may not be able to see, or copy, your project-related health information until after the project has been completed; otherwise, it could affect the study. You may ask the research doctor for updated information on what data he/she has recorded for you, and you can request corrections of any errors in the recorded data

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**

*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**