Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Transvaginal ultrasound and Photoacoustic Imaging of the Ovary (High Risk Patients)

Principal Investigator: Cary Siegel, MD

Research Team Contact: Megan Luther (314) 747-2012

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are at increased risk for ovarian cancer, you would like to be monitored before making a decision to have your ovaries and tubes removed surgically and you are over the age of 18.

The purpose of this research study is to develop procedures for imaging tissue of the ovary in order to better evaluate ovarian disease and to study how these imaging techniques might work together or separately to improve our ability to detect ovarian cancer. The research tool combines conventional ultrasound imaging with Photoacoustic imaging (PAI). Photoacoustic Imaging is an imaging technique that does not require ionizing radiation (radiation with enough energy that it causes an atom to be charged) or the use of injected dyes. This imaging technique is currently under investigation and is similar to conventional ultrasound imaging, in that a handheld probe is used to take pictures of internal structures within the body. In conventional ultrasound imaging, sound waves are sent into the body and echoes are received by the probe to form an image. By comparison PAI uses short pulses of laser light to generate ultrasound waves within the body that are received by the probe to form corresponding images.

Being in this research study does not take the place of routine physical exams or visits to your own doctor and should not be relied on to diagnose or treat medical problems.

The photoacoustic imaging device is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate in this study, you will undergo an abdominal and transvaginal ultrasound followed by the photoacoustic imaging (PAI) that will be performed in the Radiology Department at Washington University. Imaging will be performed at the same time of your standard of care (SOC) ultrasound approximately every six months for up to four and a half years for a total of up to ten, depending on if you decide to have your ovary(ies) and tubes removed surgically.

At your visit, you will be asked to change into a gown and empty your bladder before the start of the ultrasound. You will be placed supine (on your back) with both feet in the stirrups with a blanket or sheet covering you. For the transvaginal part of the ultrasound, the transvaginal ultrasound probe will either be inserted by the physician or ultrasound technician; whichever is more comfortable. Once the transvaginal ultrasound probe has identified the ovaries, ultrasound images will be taken a physician will review the images and determine if any more images are necessary, and the probe will be withdrawn. The physician may also perform an abdominal ultrasound. A small amount of ultrasound gel will be applied to your abdomen as is standard for conventional ultrasound examinations. Following this, a second transvaginal probe, consisting of a vaginal ultrasound probe with photoacoustic (PA) sensors attached will be inserted into your vagina. Images will be taken in the same way as the transvaginal ultrasound. Image data of both ultrasound and photoacoustic imaging (PAI) will be captured and displayed on the screen. This second imaging procedure will take about 10 to 15 minutes.

When you and your physician decide to schedule your standard of care surgery to have your ovary(ies) removed, the ovary(ies) that is(are) being removed will be examined by one of the pathologists here at Washington University for clinical evaluation. Then the removed ovary(ies) will be sent to the laboratory for additional study imaging. If your ovary(ies) is(are) not available for additional study imaging, we will still use the data collected during imaging before your ovary(ies) was(were) removed. There will be no additional tissue removed other than what is necessary for your health and that you have consented to having removed per standard of care.

In addition, study relevant demographic and clinical information will be collected from you after you sign the consent form. This will include your name, medical record number, date of birth, age, ethnic origin, as well as information related to your menstrual history, pregnancy history, birth control use and whether you have certain gene mutations (such as BRCA1 or HER2). Information about your family's medical history will also be collected. This data will be used for research purposes. Information obtained for medical purposes will also be used for this study and placed in your research record. This will include ultrasound exam results, pathology results, diagnosis of the condition in your ovary(s) and surgical notes.

The specimens will be used to help determine if the study imaging equipment will help to detect ovarian cancer at an early stage and help us understand how ovarian cancer develops. Your sample will be provided to the laboratory for imaging with your identifiable information (such as your name and medical records number) after being evaluated by one of our pathologists at Washington University. The laboratory imaging will be done in the Radiology Department at Washington University. Once the imaging studies are completed, the ovary that was imaged will be sent to the pathology department for diagnosis. Your identification information will not be recorded but will ensure match with your pathology record.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately **50** people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last until your surgery is completed, which could be up to five years.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Ultrasound Risks:

There is no known risk to ultrasound except for a small amount of discomfort from the probe,

Photoacoustic Imaging Risks:

Photoacoustic imaging involves class 4 lasers (class 4 is a rating that describes the energy of the laser). Most industrial, scientific, military, and medical lasers are in this category; they are associated with possible risk of eye injury. To prevent eye injury, the light pulses will be turned on only after the probe has been inserted with full contact inside the vagina and turned off before the probe is withdrawn from the vagina. The researcher will also make sure that your skin isn't exposed to the lasers for longer than is safe. The risk of skin damage, such as a burn, is also extremely small. There could be a small amount of discomfort from the Photoacoustic imaging probe.

When the tissue sample of the ovary(ies) is(are) imaged after it(they) is(are) taken out of your body, the sample will have to leave the surgical pathology laboratory and be transported to a research space for a period of up to one hour, before being returned to surgical pathology. During this time they will be handled by research staff rather than clinical staff. There is a small chance that this will negatively affect the processing of your tissue, although we will make every effort to prevent this.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study by improving the ability to detect the spread of or early ovarian cancer.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. You will be paid by check and it will be mailed directly to you approximately 3 weeks after the completion of your visit. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

- **$50.00 for each visit**
- **Total of up to $500**

WHO IS FUNDING THIS STUDY?

National Institutes of Health is funding this research study. This means that Washington University is receiving payments from National Institutes of Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from National Institutes of Health for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at **Cary Siegel, MD (314) 362-2928** and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University**.** If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institutes of Health
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives, to complete Hospital or University responsibilities

- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your protected health information relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your health care records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

To help protect your confidentiality, your name will not be included in the study database; you will be assigned a unique patient identification number. Only engaged study team members will all have access to your information because they are who match the pathology to the images. All information will be stored on password protected computers or locked in pathology. Ovarian images, specimens, slides and data will be coded before being sent, stored and analyzed by the scientists at Washington University to protect your personal information. When transporting specimens, the specimen will be placed inside a box for safe transportation. During transporting of the specimen the care and custody of the specimen will be with the study coordinator.

The research team will make sure information cannot be linked to you. A spreadsheet will be generated which identifies each subject by a unique patient identification number so that HIPPA information will not be disclosed. This spreadsheet will be stored in a HIPPA secure location. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical

records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because:

- The researcher believes that it is not in your best interest to stay in the study
- You become ineligible to participate

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Cary Siegel, MD (314) 362-2928 or Megan Luther, (314) 747-2012.**

If you experience a research-related injury, please contact: **Cary Siegel, MD (314) 362-2928 or Megan Luther, (314) 747-2012.**

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 10/06/26.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

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(Name of Person who Obtained Consent - printed)