INFORMED CONSENT DOCUMENT

Project Title: Sexual Dysfunction in Gynecologic Oncology Patients

Principal Investigator: **David Bender, MD**

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This consent form describes the research study to help you decide if you want to participate. This form 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 as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- 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 are inviting you to participate in this research study because you may have gynecologic cancer.

The purpose of this research study is to look at sexual functioning in cancer survivors and how it affects quality of life. Another purpose is to see if lidocaine can help with sexual-related discomfort and functioning in women who have had surgery for their cancer.

Lidocaine is a medicine that helps relieve pain and is an ingredient in a lot of over-the-counter pain gels and ointments. We would like to see how it could affect any possible discomfort that a woman could experience after surgery for gynecologic cancer.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 120 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to one year. You will complete questionnaires four times during your regular visits to the gynecologic oncology clinic. The questionnaires may add about 30 minutes to your regular clinic visit.

WHAT WILL HAPPEN DURING THIS STUDY?

Summary:
If you agree to participate in the study, you will complete a set of questionnaires at four time points and use a solution supplied by the research team when you have sexual intercourse. You will also keep track of your sexual encounters and pain levels during sex while you are participating in the study. The questionnaires will take about 30 minutes to complete.

Timeline:
Before your planned surgery, you will complete a set of questionnaires about your health, daily living, sexual encounters, pain, and general questions about how you are feeling. This will happen at one of your visits to the doctor's office. You will also have a physical exam that is part of your regular cancer care during these visits.

Then you will have your surgery.

Twelve weeks after your surgery, you will return to the doctor's office for a routine exam and to complete the same set of surveys as before your surgery. You will then be given a solution to use when you have sexual encounters that you apply to the outside of your vagina.

> The solution will either contain lidocaine (a numbing medication) or it will be a placebo and contain no active ingredient. You will be randomly assigned to receive the lidocaine or placebo. This means that whichever study treatment you receive will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of receiving either of the study solutions. The placebo solution will look like the solution with the active lidocaine, so you won't know if you have the lidocaine or the placebo. Neither you nor your doctor will know what type of solution you will have while you are using it in the study, but we will be able to get this information quickly if necessary.
>
> To use the solution, you will soak three cotton balls in about two teaspoons of the solution. You will then hold the cotton balls on the skin just outside of your vagina for a minute before you have intercourse. You will get further detailed instructions about how to use the solution from your study doctor or the study team.

Please do NOT use any other lubricants or aids for sexual intercourse while you are participating in this study.

Twelve weeks later, you will come back to the doctor's office and complete the same set of surveys again and have a routine physical exam.

You will continue to use the solution and record your pain level when you have sexual encounters.

Finally, twelve weeks after this, you will return to the doctor's office for a routine physical exam and complete the same set of surveys for a fourth time.

After you have completed this portion of the study and about 9 months after your surgery, your doctor

can discuss with you any future recommendations about sexual health and pain management. However, you may not know which solution you received yet.

All of these visits will occur at the same time as your regular cancer care follow-up visits to the doctor's office, which include physical exams, so there won't be any extra office visits necessary to be in the study.

Information will be collected from your medical record to support the research study, such as your age and disease history and information from your physical examinations. We will not enter any information from the research study procedures or the questionnaires into your medical chart.

Unblinding:
You will be told which solution you were randomized to receive at the end of the study, which may be after your last study visit. You will receive a letter in the mail telling you which solution you received during the study.

You will be told which solution you received during the study only if it is medically necessary (for example, if you are having a reaction and need to know which solution is used to treat you properly).

If you are unblinded and told which solution you are getting during your participation in the study, you will not continue to participate.

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.

The use of the numbing solution (lidocaine) can rarely cause the following allergic reaction: Itching or hives that can produce swelling in your face or hands, swelling or tingling in your mouth or throat or chest tightness (which can cause trouble breathing).

Also very uncommon reactions can include: blurred or double vision; confusion, dizziness, lightheadedness, or drowsiness; chest pain, or an uneven heartbeat; skin rash; swelling in the area where this medicine is applied; and trembling (shaking).

These risks could also affect your sexual partner since they may have contact with the solution.

You may feel uncomfortable answering some of the questions on the surveys. You are free to skip any questions you do not want to answer.

The study staff will notify appropriate personnel/authorities if you indicate thoughts of harming yourself or others.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because we can learn about sexual function in cancer survivors and know if something like a numbing solution might help these women have better sexual health and overall life satisfaction.

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 not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The Iowa Cancer Consortium is funding this research study. This means that the University of Iowa is receiving payments from the Iowa Cancer Consortium 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 Iowa Cancer Consortium for conducting this study.

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

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that 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.

- federal government regulatory agencies,
- The Iowa Cancer Consortium
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will only use random study ID numbers to identify you when possible and keep any information in locked offices or secure computer systems. The ID number will not include anything that will identify you personally. 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.

The University of Iowa Hospitals and Clinics generally requires that we document in your medical record chart that you are participating in this study. The information included in the chart will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies and the University of Iowa Institutional Review Boards and support staff. The sponsor, the Iowa Cancer Consortium, may also inspect any part of your medical record for the purposes of auditing the conduct of the study.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting University of Iowa Health Care. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. David Bender at University of Iowa Hospitals and Clinics, Department of Obstetrics and Gynecology, 200 Hawkins Drive, 31506 PFP, Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

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. 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.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because you aren't following the instructions or if the solution becomes unavailable or if the study doctor feels it is best for you to discontinue.

FOR IRB USE ONLY
APPROVED BY: IRB-01
IRB ID #: 201609770
APPROVAL DATE: 05/29/19
EXPIRATION DATE: 01/10/20

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself or experience a research-related injury, please contact: Dr. David Bender at (319) 356-2015.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document 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 signing this Informed Consent Document. 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 copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 01/10/20.

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

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