Consent for Participation in a Research Study

Title of Research Study: TAP 1302: Endometriosis Specimen Bank (functioning under the Northwell Health Tissue Donation Program, Global Collection Protocol)

Principal Investigator: Peter K. Gregersen, MD (Feinstein Institute for Medical Research)

This consent version to be used for women scheduled for surgical treatment of endometriosis.

Introduction

You are being asked to join a research study. The purpose of a research study is to answer specific questions about medical conditions.
This consent form will explain:

- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?

The purpose of the research is to learn more about endometriosis. To do this we will establish a tissue bank. We will collect and store tissue, blood, DNA and RNA (the genetic material in your cells). Cells obtained from your samples may be grown in the lab for either short periods of time, or indefinitely. The samples will be used for future genetic research as well as other types of research to learn more about endometriosis as well as possibly other diseases. We will also collect information about your age, ethnicity and medical/health history. We hope future studies using the tissue bank samples will lead to improved understanding of endometriosis and ultimately new and effective diagnostic and treatment options for women with endometriosis in the future.

This study is part of the Tissue Donation Program, at The Feinstein Institute for Medical Research, of Northwell Health. The Tissue Donation Program (TDP) oversees a data and tissue bank, developed to support research on different diseases and conditions. The TDP collects and stores many types of samples in the Boas Center Biorepository (BCB), along with health history information from participants.

The Tissue Donation Program allows researchers at Northwell Health, as well as researchers at other academic institutions and at for-profit companies to access stored samples after their proposed research has received approval from the Committee for Participant Protection. This committee reviews research projects that request banked samples and assures that they are ethical

and appropriate research. The TDP may receive compensation to cover the cost of collection, storage and shipping of samples to researchers outside of Northwell Health.

You are being asked to join this research study because you are scheduled to have surgery for endometriosis. Endometriosis is a condition in which the tissue that lines the uterus grows outside of the uterus on other organs or structures in the body.

If you are under the age of 18 years, pregnant or breast feeding you cannot participate in this study.

If you are scheduled to have surgery, you will sign a separate consent form for the surgical procedure you will be undergoing.

How many people will take part in this study?
We plan to enroll about 200 participants per year. They will include individuals who are undergoing endometriosis surgery as part of their standard-of-care, individuals with a history of endometriosis who have already had surgery or do not require surgery, and first degree relatives of family members (female and male) of women with endometriosis.

What will happen in this research study?

1. Provide a blood sample of 30cc (2 tablespoons). We will collect the sample before your surgery or during your operation. The blood sample will be used to obtain DNA and RNA and plasma and/or serum (the liquid part of your blood).

2. Donate a sample of tissue collected at the time of surgery.
   During your surgery your surgeon will remove the endometriosis growths that are outside of your uterus and causing symptoms. The removed tissue is sent to Pathology for evaluation. In many cases, all of the removed tissue is not needed for evaluation. Removed tissue that is not needed by the pathologists will be collected for the endometriosis tissue bank.

3. Participation will require signing consent: via email (RedCap) or in person. In addition we ask for your permission to receive text messages regarding follow up.

4. Collect a sample of menstrual flow, using a reusable menstrual cup (The DivaCup). This is a flexible healthcare grade silicone cup worn inside the vagina to collect menstrual blood. You will be able to do this at home during the first three days of your period. You will be asked to collect menstrual flow with a menstrual cup for a 6-12 hour period. Some women may be asked to collect multiple menstrual flow samples for up to 48 hours. The DivaCup holds up to 1 ounce (2 tablespoons). The entire, average monthly menstrual blood flow is approximately 1 to 2 ounces (2 – 4 tablespoons). The DivaCup can be worn up to a maximum of 12 consecutive hours before removing, washing and re-inserting. By monitoring the fullness of the cup, you will learn how often to empty it according to you needs. The DivaCup should be washed with a mild, unscented soap and warm water before reinserting. .

Collection of a menstrual blood sample is optional. If you agree to collect this sample you will need to place the menstrual blood collected each time the cup is removed into a sample collection container(s) we will provide. We will provide a kit containing a menstrual cup, along with instructions for use and return shipping materials or instructions for having the sample returned to us via courier.

You will receive a copy of the manufacturer's User Guide regarding menstrual cup use and are responsible to read it before using the cup. We encourage you to speak with a Customer Care representative from The DivaCup if you have questions about how to use the DivaCup. You should also consult your physician with any gynecological / medical questions.

5. Complete a questionnaire about your medical and family history. This may be done before or after your surgery.

6. Complete a questionnaire about how endometriosis has affected your quality of life. This may be done before or after your surgery.

7. Complete the WERF (World Endometriosis Research Foundation) Form which asks extensive gynecological questions.

8. Allow access to your medical records in the future. We will only collect information that is needed for the research, such as date of onset of endometriosis, disease duration, clinical characteristics of your disease, medications and results of lab tests and x-rays. Information about your medical condition may be collected indefinitely, or until you request that we stop collecting it.

9. Allow us to store a copy of the video of your surgical procedure, without any identifying information on it.

10. Agree to let us contact you in the future to obtain follow-up information.

11. Allow us to collect a portion of the tissue that will be stored permanently in the Department of Pathology, once all analysis has been completed.

How long will you be in this study?
Answering the health history questions, the quality of life questions and providing a blood sample will take about an hour. If possible, we will collect the blood sample at the time of another blood test or during your surgery. Collecting surgical tissue will not affect how long the surgery takes. Collecting a menstrual flow sample should take between 6-12 hours. Once the samples described in this consent are collected and you have completed the study questionnaires, your active participation in this research will be over. The time period in which we may re-contact you to request additional health information is indefinite, as this study will go on for many years and it is not possible to know when we may want to re-contact you, if ever. Your samples and information will be kept indefinitely, for use in future research.

What are the risks of the research study? What could go wrong?

Blood Collection: There are no major risks of having blood drawn. It can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained staff will draw your blood.

Menstrual Cup: Collecting a sample of menstrual blood via a menstrual cup is safe when used as directed. The cup should not be worn for more than 12 hours at a time. You should NOT use the menstrual cup if you are currently using an internal birth control, such as an IUD, or if you have had endometriosis surgery or other pelvic surgery within the past year, unless your surgeon tells you it is okay to do so within the first year after surgery. There is a low occurrence rate of vaginal or urinary tract infections in women using a menstrual cup, similar to women who use tampons.

Sometimes a woman may have difficulty removing the DivaCup after insertion. This can cause anxiety and make it more difficult to remove. Rarely medical assistance may be required to remove the cup. It is important to read the DivaCup User Guide thoroughly before trying the DivaCup. You may want to consult with your doctor or the Customer Care Team at DivaCup (support@divacup.com) for questions or concerns before trying the DivaCup.

Collection of Surgical Specimen: If you are scheduled to undergo surgery, allowing us to collect a portion of the tissue that are removed as part of your normal surgical care and are not required for evaluation by pathology does not increase the risks of surgery.

Genetic Research: You should not expect to get individual results of genetic research that might be done on your samples. Researchers must study samples and information from many people over many years before they can know if the results have meaning. We will send a newsletter once a year to people who take part in the study. The newsletter will give general updates about the studies being done.

Research test results will not be given to anyone including your family members, your health care providers, insurance companies and/ or employers.

There is a risk to your privacy and confidentiality. We take your privacy very seriously and take extensive measures to protect you identity. Even with strong protections in place there is a small

risk that the confidentiality of your personal information or information learned from the genetic sample you provide for this study could become known by unauthorized individuals.

When we share samples or data, they are stripped of all identifiers such as name and date of birth. We only share samples with individuals who agree not to try and uncover the identity of the samples/data. However, we cannot control the actions of others once data or samples are shared and cannot say for certain that in the future new technology will not allow re-identification of genetic data or samples.

Unknown Side Effects: As with any procedure, there might be side effects that are unknown at this time. You will be closely watched for side effects. You should report any unusual events to the study staff.

Sharing of Samples: If we share any of your samples with researchers, then we will remove identifiers such as name or date of birth before sharing them. However, in some circumstances, when an investigator requests to receive freshly collected samples, we will not be able to prevent the investigator from knowing the date the sample was collected. This is considered identifying information because it may allow the investigator to determine who the sample was collected from.

What are the benefits of this research study?
You will not benefit directly from participating in this study. However knowledge may be gained that could increase the understanding of endometriosis and possibly other conditions and benefit others in the future.

If you do not want to take part in this research study, what are your other choices?
You can choose not to participate in this study.

Are there any costs for being in this research study?
There will be no costs to you for participating in this research. The costs associated with your scheduled surgery and other standard of care medical expenses will not be covered by this research project. You will be responsible for these costs, either directly or through your medical insurance coverage. Since you will be receiving text messages, you may be charged for digital communications from a service provider, such as a phone company.

Will you receive any payments for participating in this research study?
You will be compensated $50 for providing each 12 hour menstrual blood flow sample.

If the total payment you receive from Northwell Health, during this year, is equal to $600 or more, the payment is required to be reported to IRS. Although this study does not pay $600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

If the research procedures marketable procedures, will you receive any payment?
If this research project, or the operation of the data and tissue bank, results in the development of any marketable product, there are no plans for you to share in any profits.

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data or samples already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We will collect the results of study questionnaires. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called <u>authorization.</u> If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

- Other researchers
- Occasionally, your phenotype (observable characteristics) may lead to the direct interaction of a research scientist with you. In this case, the Rose Study team will offer you a referral to the particular study. If interested in participating in their study, you will contact the user-investigator (i.e., investigator of the study you wish to participate in) directly and sign a separate consent for their IRB approved protocol; thus allowing shared identified information between the user-investigator and the ROSE Study/TDP.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies.
- Representatives from the Northwell Health Institutional Review Board (IRB - the committee that reviews research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it will be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, or for any questions related to your health information, you may contact the Research Privacy Officer at 516-321-2100.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Peter K. Gregersen
The Feinstein Institute for Medical Research
350 Community Drive
Manhasset, NY 11030

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information or samples any further. You may also need to leave the research study if we cannot collect any more health information. We will destroy your sample(s) to the best of our ability, but it may not be possible to retrieve information or samples that have already been used in the research, prior to your request to stop using them.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This means that the researchers cannot be forced to identify you or turn over any information contained in our research record, even under a court subpoena. The Certificate does not mean the Secretary of DHHS approves or disapproves of the project. It adds special protection for the research information about you. However, researchers may provide information to appropriate authorities if harm to you, harm to others, or child abuse becomes a concern. In addition the federal agency funding this research may see your information if it audits us.

A Certificate of Confidentiality does not prevent you from voluntarily giving information about yourself or your involvement in this research to other people. However, if you agree that an insurer, employer, or any other person may receive your research information, then the researchers may not use the Certificate to withhold that information.

Does the investigator of this study receive money if you take part?
Funding for this research study is provided by the Endometriosis Foundation of America. The funding is used to support the activities of the Tissue Donation Program (TDP) for the costs of conducting the study including paying the study personnel. Compensation is not based upon the number of people enrolled in the study. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about the study?
If you have any questions about this study, you may call the principal investigator, Peter Gregersen, MD at (516) 562-1542 or. If you have questions about side effects or injury caused by this research you should call, Peter Gregersen, MD at (516) 562-1542. If you experience a medical emergency call 911 or go the nearest emergency room. If you have questions regarding your rights as a research subject or concerns about the research project, you should call the Office of the Institutional Review Board at 516-321-2100. A signed copy of this consent form will be given to you.

Summary:
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

☐ I am willing to receive text messages about follow up studies
My Cell phone number: ☐☐☐-☐☐☐☐-☐☐☐☐

My cell phone carrier: ☐ AT&T ☐ Verizon ☐ Sprint ☐ T-Mobile

Other (specify)_____

Subject's printed name	Subject's signature	Date
Witness's printed name	Witness's signature	Date

Investigator's Statement:
In addition to advising the above subject about this research, I have offered an opportunity for further explanation of the risks and discomforts which are, or maybe associated with this study and to answer any further questions relating to it.

Investigator's signature	Investigator's printed name	Date