### Northwestern University

# National Physicians Cooperative of the Oncofertility Consortium at Northwestern University

# Division of Fertility Preservation

# Department of Obstetrics and Gynecology

# **CONSENT FORM AND AUTHORIZATION FOR RESEARCH**

**Title: Ovarian Tissue Freezing For Fertility Preservation In Women Facing A Fertility Threatening Medical Diagnosis Or Treatment Regimen: A Study By The National Physicians Cooperative of the Oncofertility Consortium At Northwestern University**

**Principal Investigator: Ralph R. Kazer, MD**

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You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study and the way us, Northwestern University, would like to use information about you and your health.

## What is the reason for doing this study?

You are being asked to participate in this research study because you are a woman who will receive treatment for a medical condition which may result in infertility. You will be undergoing one of the following treatments and wish to preserve your ovarian tissue for the purpose of initiating a pregnancy in the future:

* Women who will undergo surgery, drug treatment, chemotherapy or radiation therapy which is expected to result in a loss or impairment of ovarian function and/or infertility. Although not all surgery, drug treatment, chemotherapy or radiation treatments affect fertility (the ability to become pregnant), the treatments you will receive are expected to affect your ovarian function and are likely to cause you to become sterile (unable to become pregnant) after therapy is finished.
* Women who will undergo surgery to remove one or both ovaries or portions of the ovaries as a way of treating or preventing a particular disease who wish to preserve their fertility.

In order to potentially preserve fertility, ovarian tissue can be surgically removed, frozen, and stored. This tissue can be thawed and re-implanted to restore fertility, and such methods have resulted in human births. There is also active research to develop new ways in which this frozen ovarian tissue can be used to restore fertility. Presently, the technique of freezing ovarian tissue is considered experimental, and so thawing and subsequent use of the tissue to initiate a pregnancy must be performed as part of a research program. By participating in this research a portion of your ovarian tissue will be frozen for your own use and a portion will be donated for research.

Your participation may advance our understanding of how to successfully freeze and thaw ovarian tissue in a manner that permits subsequent use by patients at some point in the future. Your participation may also advance our knowledge of how to successfully mature follicles and oocytes (eggs) that are contained in these tissues which may help you or others in the future. If tissue is frozen for your own use, you may have a means to restore your fertility in the future. However, there is a significant possibility that there may be no direct benefit to you from your participation in this research study.

## What you will do if you choose to be in this study?

If you choose to participate in this study, and are interested in fertility preservation, a portion of your ovarian tissue will be cryopreserved and stored for your later use and a portion will be donated for research. In the future, you can determine how and at what institution you wish to use your own tissue for the purposes of attempting to achieve a pregnancy. Your care at that time will be determined by the physician taking care of you.

We will contact you by phone or mail until you have used your tissue or dropped out of the study to follow your medical and fertility status over time; ask questions about any future use of your frozen tissue and the possible outcomes of your fertility preservation treatment.

**Procedures:**

**For women who will receive chemotherapy, drug treatment or radiation therapy**

**Pre-Operative Assessment:** If you are enrolling in this research study because you are a woman who will be undergoing chemotherapy, drug treatment or radiation therapy, you will be evaluated by your oncologist or gynecologic surgeon and have blood drawn (about 6 tablespoons) to confirm that you are eligible for this study. This blood will be used to measure FSH, estradiol and AMH, hormones in your blood, which give us an indication of whether your ovaries still contain a large number of healthy eggs. If this blood test indicates that you may not have eggs remaining in your ovaries, you will not be eligible for this study. You will also be evaluated by an anesthesiologist. If in his or her view, you would incur any additional risk of anesthesia by virtue of your disease or your general state of health, you will not be eligible for this study. You may also meet with a clinical psychologist as part of your evaluation. This will require 1 or 2 additional office visits, each lasting between 30-60 minutes.

**Surgery:** You will undergo a surgical procedure called a laparoscopy under general anesthesia (you will be asleep) to remove one of your ovaries. This surgical procedure will be performed on you solely for the purpose of performing ovarian tissue cryopreservation which is an experimental procedure. It is not required for the treatment of your cancer.

A telescope-like instrument (a laparoscope) will be inserted into your abdominal cavity through a small (about half an inch) incision just below your navel. Two or three other such incisions may be made to permit the introduction of other instruments into your abdomen to allow the removal of your ovary. The technique for the removal of ovarian tissue by means of laparoscopy is based on well-established surgical approaches or techniques and has a very high likelihood of success.

Your surgery is planned to be performed as an outpatient procedure (will not require an overnight hospital stay). The duration of surgery is likely to be between 45 and 60 minutes. The recovery time required prior to either resuming normal activities or initiating chemotherapy or radiation therapy is expected to be 2-3 days. Your total time spent in the hospital will be about half a day. You will not be able to drive immediately following the surgical procedure.

**For women who will have one or both ovaries or portions of their ovaries removed as treatment for a particular disease:**

**Pre-Operative Assessment:** If you are enrolling in this research study because you are having surgical removal of one or both of your ovaries or a portion of your ovaries as a way of treating or preventing a particular disease and wish to preserve your ovarian tissue for the purpose of initiating a pregnancy in the future you will be evaluated by your oncologist or gynecologic surgeon and have blood drawn (about 6 tablespoons) to confirm that you are eligible for this study. This blood will be used to measure FSH, estradiol and AMH, hormones in your blood, which give us an indication of whether your ovaries still contain a large number of healthy eggs. If this blood test indicates that you may not have eggs remaining in your ovaries, you will not be eligible for this study. Your surgery will be performed as your surgeon determines is appropriate for your medical condition.

**For all women having ovarian tissue cryopreservation:**

**Laboratory Procedures:** After surgery, a 0.5 cm cross section of the removed ovary will be sent to the Department of Pathology and examined under a microscope. You will receive a copy of this report. A report that the tissue appears to be healthy is not a guarantee that the tissue is free of cancer cells, which could grow if the tissue were re-implanted in the future. However, if the Department of Pathology finds an abnormality in this sample that appears to be cancer, they may request that all of the tissue obtained during your surgery be returned to them for a more detailed examination. If this occurs, there may be no tissue remaining for fertility preservation purposes.

**Tissue Storage**: The remaining ovarian tissue will be frozen and stored in a number of separate vials. If you participate in this study, a portion of the tissue (never more than 20% of the total tissue and any eggs that it may contain) will be used for research. This research tissue may be used either before or after it is frozen. The research portion of the tissue will not be used for any studies that involve fertilization of the oocytes (eggs) it contains. You will not be able to use the 20% of the tissue donated for research.

The remainder of the ovarian tissue will be stored for your possible future use at Reprotech, Ltd (RTL) ( Roseville Mn), an accredited long term storage facility (<http://www.reprot.com>). You will be asked to sign a separate storage agreement with Reprotech, Ltd. (RTL) that addresses the ownership, storage, shipping and future disposition of your samples. You will be responsible for the initial shipping and annual storage fee (approximately $300) and any other charges accrued (e.g. shipping to another institution, at your request). Your tissue will only be stored at Northwestern University/Northwestern Medical Faculty Foundation for a short period of time following cryopreservation while shipment to Reprotech, Ltd. (RTL) is arranged. You will retain control over your tissues and may utilize them as you deem appropriate at the institution that you choose in the future. There is no limit as to how long your samples may be stored at Reprotech provided your storage fees are paid annually. Reprotech has a financial assistance program in place for those who qualify.

During the period of time that your remaining tissue is stored, it is possible that technological advancements will progress for thawing stored ovarian tissues. If such advances take place and are found to be safe, you may request to thaw your tissue for re-implantation or egg recovery for the purpose of in vitro fertilization (IVF) in order to achieve pregnancy. At that time, your stored tissue will be transferred by Reprotech, Ltd. (RTL) to the facility of your choice at your request and at your expense. As part of your participation in this study, you will be updated on new options that are available for the use of your tissue and where those options are available. We cannot give you any information about the tissue that you donated to research since it will be de-identified (will not have your name attached to it). However, it is also possible that technological advancements to thaw the stored ovarian tissue may never occur and the tissue may not be usable. Although unlikely, it is also possible that these techniques may require approval by outside agencies (like the Food and Drug Administration) before they could be used to produce a pregnancy.

**Infectious Disease Testing:** Banking and subsequent use of ovarian tissue is regulated by the Food and Drug Administration (FDA). In order to comply with current tissue banking regulations and to be prepared for any future changes in regulations while your tissues are in storage, you will be tested and screened for a number of infectious diseases prior to banking your ovarian tissue.

These tests will include but not be limited to testing for HIV, Hepatitis B and C based on current federal regulations. The screening and tests that will be performed are the same that would be performed on an anonymous reproductive tissue donor and will also include a physical examination and questions about possible high risk behaviors as well as blood tests. In this way, the tissue could potentially be used by you or would be suitable for use in another individual (such as a gestational carrier/surrogate) in the future, if your medical diagnosis indicates that this is necessary. Your ovarian tissue will be stored with tissue having the same infectious disease status. This infectious disease testing is only required because of the tissue that is being stored for your own use and not because you are donating tissue for research. This blood may be drawn after your surgery once the tissue has actually been obtained.

You will be tested for HIV using a blood test. HIV is the term used for the virus that produces the HIV infection and may ultimately lead to AIDS. The study doctor must follow the Illinois AIDS Confidentiality Act (An Illinois law that sets up how HIV testing must be done and protects the confidentiality of information about someone's HIV status.)

In addition, a sample of your blood plasma will be stored with your ovarian tissue to permit any additional future infectious testing required under federal tissue banking regulations. Current FDA regulations about required infectious disease testing for those storing tissues are specific and must be performed on a plasma sample that is obtained within 7 days of the tissue removal. If additional tests are required by the FDA in the future, this stored plasma might be used to perform those tests. However, in spite of storing blood plasma, the plasma sample may be inadequate to perform required testing under any new regulations and you may not be able to use your tissue in the future.

**What are some of the risks and discomforts for people who are in this study?**

Taking part in this study may involve the following risks:

Laparoscopy: Risks of the laparoscopy include infection, damage to your internal organs or bleeding problems as a result of the insertion or manipulation of the laparoscopic instruments. The chance of you requiring hospitalization or more extensive surgery for the management of complications is about 1 in 1000. Such complication(s) may necessitate a delay in further chemotherapy or radiation therapy treatments for your disease. Your chance of dying as a result of such complication(s) is less than 1 in 10,000. Minor complications, such as temporary pain or bruising at the incision sites are common.

General Anesthesia: Your chance of dying from the anesthesia is less than 1 in 10,000. Minor complications, such as sore throat or short-term nausea, are quite common.

**Elective (by choice) removal of an ovary:** You have been invited to participate in this study because we expect that the treatment or surgery that you will undergo to treat your medical condition or cancer will significantly impair your future fertility. You should also know that it is possible to experience decreased fertility due to the removal of an ovary and/or to experience an early menopause caused by the loss of hormones produced by ovaries. Although we do not expect it, you may regain spontaneous ovarian function in spite of your medical treatments. In addition, it is possible that the surgery itself could cause scar tissue or damage to the remaining ovarian tissue, further decreasing your chances of spontaneous pregnancy. These circumstances are very unlikely and much less likely than your chance of losing ovarian function as a consequence of your cancer or medical treatment. You are also potentially at risk for the psychological consequences, including emotional upset, of having one ovary removed.

**Cryopreservation (freezing):** Although care will be taken, damage to your removed ovarian tissues may occur during any part of the cryopreservation (freezing), shipping and storage process. The effects of cryopreservation and storage on human ovarian tissues are not known. The risk of birth defect(s) and/or genetic damage to any child who may be born following such a procedure is also unknown. There are many medications whose effects on the ovary or egg quality are not yet known or have not yet been determined. However, thousands of children have been born following freezing of oocytes (eggs) and embryos and those freezing procedures have not resulted in an increased risk of birth defects.

The ovarian tissue removed may not yield usable eggs, or pregnancy may not result when the eggs or tissue are ultimately used.

It is also possible that technological advancements to thaw the stored ovarian tissue may not occur and the tissue may not be usable.

Some subjects may have particular risks associated with their underlying disease. If a cancer or other disease has already affected the ovarian tissue, then it may never be possible to use the tissue in the future. This may not be known until after you are healthy and wish to use your ovarian tissue.

Tissue could be lost or made unusable due to equipment failure, or unforeseeable natural disasters beyond the control of this program.

**Infectious disease testing:** Infectious disease testing and screening performed around the time of your surgery may be inadequate to permit safe use of your tissue after the long term storage of the tissue. While a sample of your blood plasma will be stored to minimize this risk, the tests required in the future may require a sample other than plasma, the plasma sample may be inadequate or it may be lost or damaged in the cryopreservation or shipping process. Infectious disease tests will include but not be limited to testing for HIV, Hepatitis B and C based on current federal regulations. Infectious disease testing may reveal an infection or disease of which you were previously unaware and which may require treatment. You will be tested for HIV. HIV is the term used for the virus that produces HIV infection and may ultimately lead to AIDS. Your blood will be taken to test for HIV. The study doctor must follow the Illinois AIDS Confidentiality Act (An Illinois law that sets up how HIV testing must be done and protects the confidentiality of information about someone's HIV status.)

**Emotional risks:** Your participation in this study may subject you to additional emotional risks beyond those directly related to your planned treatment.

**Tissue may be unavailable for freezing:** Although you may sign this consent, it is possible that there may be no tissue available for freezing. At the time of your surgery, if your surgeon or the pathologist (the physician who examines your tissue through the microscope) determines that all of your tissue is needed to diagnose your disease, then no tissue may be available for freezing. If that occurs you will not have any tissue frozen for your future use.

**There may not be enough tissue for both your use and for research:** If only a small portion of your ovarian tissue is available after your surgeon and the pathologist have made their determinations, there may not be sufficient tissue to ***both*** freeze tissue for your own use and to use for research. It is your choice what will be done under this circumstance and you will be asked below to indicate what you would want done in that circumstance.

## What are some of the benefits that are likely to result from my being in this study?

Your participation may advance our understanding of how to successfully freeze and thaw ovarian tissue in a manner that permits subsequent use by patients at some point in the future. Your participation may also advance our knowledge of how to successfully mature follicles and oocytes (eggs) that are contained in these tissues which may help others in the future. If tissue is frozen for your own use, you may have a means to restore your fertility in the future. However, there is a significant possibility that there may be no direct benefit to you from your participation in this research study.

**What other procedures or courses of treatment might be available to me?**

You do not have to take part in this research study. In addition to being in this research study, the following treatment choices are available for your condition: You have the alternative to choose not to participate in this study. If you have a partner, you have the option of undergoing treatment with *in vitro* fertilization (IVF) in order to cryopreserve (freeze) embryos for future use (embryo banking). If you do not have a partner, you have the option of undergoing a modified form of *in vitro* fertilization (IVF) in order to cryopreserve (freeze) eggs for future use (egg banking). Alternatively, you can make use of donor sperm and have conventional IVF with freezing of the resulting embryos. These procedures require several weeks to complete.

You also have the alternative of undergoing therapy with a type of medication called GnRH agonist (a protein which suppresses hormonal stimulation of your ovaries) prior to your cancer treatment. There is some evidence that such treatment reduces the risk of damage to the ovaries by either chemotherapy or radiation therapy. However, there have also been reports that its use may reduce the effectiveness of certain types of chemotherapy. This treatment is still considered experimental.

You also have the option of having your ovaries shielded from radiation or surgically moved to an area of the body away from the radiation (oophoropexy). The effectiveness of these procedures varies with the individual.

The ovarian tissue that is stored for your own use may be used for transplant back into your own body when you are ready to attempt to achieve a pregnancy. At the present time, approximately 25 pregnancies have occurred world wide using this technique. (The reports of these pregnancies were “case reports” and so did not state how often this technique is successful). Transplant of your own tissue cannot be used if you have a type of cancer in which your ovarian tissue might contain cancer cells that can “re-seed” your cancer in the future (such as ovarian cancer or some types of leukemia or lymphoma). At the present time, this procedure is not available at Northwestern but is available at other institutions in the mid-West.

In the future, your ovarian tissue may be thawed and the follicles and oocytes (eggs) it contains may be matured in the laboratory in a process called in vitro follicle maturation (IFM) and then fertilized using *in vitro* fertilization. At the present time, pregnancies and live birth have only been achieved in rodents using this technique and experiments in primates (monkeys and human) are ongoing.

Freezing of ovarian tissue is available outside of this protocol (without participating in this study).

**Are there any financial costs to being in this study*?***

You will receive no compensation for your participation in this study. You or your insurance company will be responsible for payment of all medications and medical care that would normally be part of the treatment or prevention of your condition, which may include the surgery to remove your ovary (ovaries), costs of infectious disease testing, processing and freezing of your tissue as well as pathology. How much you have to pay depends on whether or not you have health insurance and what costs your insurer will cover. If you have any questions concerning you insurance coverage, you should speak to your healthcare insurance carrier.

The research portion of your tissue will be used only for research and will not be sold. The research done with your tissue may lead to the development of new products in the future. No compensation will be given to you now or in the future for the use of these samples. The portion of your tissue that is for your own use will remain under your control and expenses associated with any future use of that tissue are your responsibility. As part of your participation in this study, you will be updated on new options that available for the use of your tissue and where those options are available.

Charges for infectious disease testing will be your responsibility since this testing is only required for your use of your own tissue (approximately $200) and is not part of the research project. We will bill this to your insurance and any portion that is not covered will be your responsibility.

You will be responsible for the initial shipping and annual storage fee at ReproTech, Ltd. (approximately $300) and any other charges accrued (e.g. shipping to another institution, at your request). Reprotech has a financial assistance program in place for those who qualify. You will enter into a separate storage agreement with Reprotech to cover the storage and disposition of your tissue.

**If there is insufficient ovarian tissue to use for** *both* **research and your own use**, then you will indicate what should be done with your tissue: all frozen for your own use or all donated to research. If there is ***not*** sufficient tissue for ***both*** your own use and for research, please ***initial*** the option you would choose:

\_\_\_\_\_\_\_\_ My ovarian tissue should ***all*** be frozen for my own use in the future at my expense. I understand that that some costs for fertility preservation will be my responsibility.

\_\_\_\_\_\_\_\_ My ovarian tissue should ***all*** be donated to research. I understand that none will be frozen or available for my own use and that there will be no charges or compensation for this donation.

**What if I want my ovarian tissue frozen for my own use and do not want to donate any portion to research?**

Your ovarian tissue can be frozen for your own use only and you can decide not to donate any to the research effort but to participate in the long term follow-up on how you use this tissue. All expenses not covered by your insurance (including your surgery) will be your responsibility. Your tissue is for your own use will remain under your control; expenses associated with any future use of that tissue are your responsibility. Charges for infectious disease testing are your responsibility since this testing is only required for your use of your own tissue (approximately $200). Insurance usually covers the infectious disease testing. As part of your participation in this study, you will be updated on new options that available for the use of your tissue and where those options are available.

Please indicate that you want to exercise this option by **initialing** before the statement; if this statement does not reflect your wishes, *please cross it out*:

\_\_\_\_\_\_\_ I do not wish to donate ***any*** of my tissue to research and request that my ovarian tissue be frozen for my own use only regardless of the amount of tissue available. I will participate in the long term follow-up on my use of this tissue as described. I understand and agree to the financial responsibilities described above.

**What should I do if I am injured as a result of being in this study?**

In the event of injury or illness as a result of study medications or study procedures, you should seek medical treatment through your physician or treatment center of choice. You should promptly notify the study doctor in event of any illness or injury. Payment for this treatment will be your responsibility.

**If I have questions or concerns about this research study, whom can I call?**

You can call us with your questions or concerns. Dr. Ralph Kazer at (312) 695-7269 is the person in charge of this research study. You can also call Kristin Smith, Patient Navigator for the Oncofertility Consortium at 312-503-3378 with questions about this research study. In the event of an injury or illness as a result of the study, you should contact Dr. Ralph Kazer at (312) 695-7269.

**What are my rights as a research subject?**

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment for which you are otherwise entitled.

Any new findings developed during the course of this research that may affect your willingness to continue in this study will be shared with you.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Office for the Protection of Research Subjects. You can call them at 312-503-9338.

**What about my confidentiality and privacy rights?**

We are committed to respect your privacy and to keep your personal information confidential.

When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number.

Your health information we may collect and use for this research includes:

* all information in a medical record,
* results of physical examinations,
* medical history,
* lab tests

The study doctor must report positive HIV tests to the Illinois Department of Public Health (IDPH). The IDPH keeps track of all persons in the state with positive HIV tests. The database that keeps track of this information is coded so that your name does not appear with your HIV status. You are given a unique identification number. This helps keep your name private.

You are also giving permission to the following groups of people to give information about you (described above) to the researchers for this study:

All current and previous health care providers, including but not limited to Northwestern Medical Faculty Foundation (NMFF) and Northwestern Memorial Hospital (NMH), National Cancer Institute and Reprotech, Ltd.

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office].

* Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office of Research, and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),
* Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications or presentations at scientific meetings. No personal identifiers will be used in any publication or presentation.

**Please note that:**

* You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
* You may change your mind and revoke (“take back”) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to: Ralph Kazer, MD, Northwestern Medical Faculty Foundation, Department of Obstetrics and Gynecology, 675 N St. Clair Street, Suite 14-200, Chicago IL 60611, (312) 695-7269.
* Unless you revoke your consent, it will not expire.
* If you revoke (“take back”) your consent to use any blood or tissue taken for the study, the Principal Investigator will make sure that the research specimens are destroyed (the tissue that is for your own use will not be destroyed, unless you request that separately in writing) or will make sure that all information that could identify you is removed from these samples. You will not be contacted for follow-up.

**Consent Summary:**

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction. If I have additional questions, I have been told who to contact. I agree to participate in the research study described above and will receive a copy of this consent form. I will receive a copy of this consent form after I sign it. I have initialed the sections as indicated above on page 8..

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Subject’s Printed Name

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Subject’s Signature Date

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Printed Name of Person Obtaining Consent

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Signature of Person Obtaining Consent Date