**[INSERT YOUR Center for Fertility and Reproductive Endocrinology NAME HERE]**

Phone: xxx-xxx-xxx

Fax: xxx-xxx-xxx

**TITLE**: **Testicular tissue cryopreservation for fertility preservation in patients facing infertility-causing diseases or treatment regimens.**

**(Reconsent for Subjects at age of 18)**

**PRINCIPAL INVESTIGATOR:**  [Add PI name and phone number here]

INVESTIGATORS: [List all members of the study team here]

**CONSENT TO BE A SUBJECT IN A MEDICAL EXPERIMENT AND AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF IDENTIFIABLE MEDICAL INFORMATION (PROTECTED HEALTH INFORMATION) FOR RESEARCH PURPOSES**

***What am I being asked to do?***

You are invited to continue taking part in a research study at [INSERT YOUR CENTER NAME HERE] that is participating in a Coordinating Center Protocol for Testicular Tissue Cryopreservation with the Fertility Preservation Program at Magee-Womens Hospital (MWH) in Pittsburgh It is important that you read or have read to you several general principles that apply to all persons who take part in this study: (a) taking part in the study is entirely voluntary; (b) personal benefit may not result from taking part in the study, and (c) you may withdraw from the study at any time without penalty or loss of any benefits to which you are entitled. The purpose of the study, risks, benefits, inconveniences, discomforts, and other pertinent information are discussed below. You are urged to discuss any questions you have about this study with the doctors who explain it to you.

You are being asked to continue participating in this research study because you have received treatment for a medical condition which may result in infertility (inability to have your own children), and you have preserved your testicular tissue for the purpose of possibly allowing you to have your own children in the future. Your continued participation will allow continued storage of your tissue for potential future use and will allow researchers to follow your general health and fertility.

***Why Is This Study Being Done?***

The main purpose of the proposed study is to develop techniques for long-term preservation of testicular function through cryopreservation (freezing) of testicular tissue and/or cells prior to therapies that are likely to cause infertility (e.g., chemotherapy, radiation). This study will store frozen testicular tissue and/or cells for you as a potential resource to allow medical procedures to attempt to restore your fertility in the future using experimental techniques currently under development. The study also provided a portion of your tissue for research to advance our understanding of:

1. The best techniques for freezing testicular tissue/cells.
2. Methods of identifying and removing contaminating cancer cells in testicular tissue.

***How many people will take part in this study?***

We expect that the Coordinating Center and allied recruitment sites, including [INSERT YOUR CENTER NAME HERE], will enroll approximately 25 subjects of any age each year.

***What happened on this study that was research?***

When you and/or your parents initially gave consent for your participation in this study, you underwent a surgical procedure to harvest your testicular tissue before you received a treatment that was deemed likely to cause your future infertility. The harvested testicular tissue was evaluated by a pathologist, a portion was donated for use in laboratory research, and a portion was cryopreserved for your later potential use. For this latter portion of your testicular tissue, you will determine how you wish to use this tissue in the future and at which institution. After the surgical procedure, there was one post-operative checkup to make sure you were healing as expected. We have also contacted you every year by phone or mail to follow your medical and fertility status over time, and ask questions about any future use of your frozen tissue and the possible outcomes of your fertility preservation treatment.

***What will happen on this study that is research if I continue to participate?***

If you choose to continue participating in this research study, we will continue to store your testicular tissue/cells that were frozen for your own future use. We will also contact you every year by phone or mail until you have 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.

**Tissue Storage.** Some of your frozen testicular tissue/cells was stored for your own potential future. These samples were assigned a code and the information linking the code with your identity and were stored in a separate secure location in accordance with an agreement you and/or your parents signed with Reprotech, Ltd. These tissues/cells were frozen for your own use and will continue to be stored until you use the samples, withdraw from the study, or die, depending on the agreement you will sign with Reprotech, Ltd. As a part of this study, a certain percentage of your tissue was designated for scientific experiments. For instance, one or more of the vials may be thawed to permit studies designed to determine how best to recover cells that can develop into sperm from the tissue. Also, some of the tissue dedicated for scientific experiments may have been studied prior to freezing. The research portion of the tissue has not and will not be used for any studies that involve fertilization of eggs. The tissue donated for research will not be usable by you.

**Blood Plasma.** In addition, a sample of your blood plasma was stored along with your testicular tissue to permit any future testing required under federal tissue banking regulations. We will continue to store this sample of your blood plasma with your testicular tissue.

***How long am I in the study?***

We will collect personal and medical information about how you are doing each year for as long as you continue to participate in this study (until your written request to withdraw from the study has been received). There is no defined end-point of this study. Each year we will ask you for the following information: the current status of your primary disease or condition, any additional treatments you have received (such as other chemotherapies, radiation, or surgery), the dates of any additional therapies, any new diseases or conditions you have been diagnosed with since enrolling in the study, any side-effects of treatments, death, your current marital status, your sexual history, if your sexual partner(s) has become pregnant by you and had any children, and if you and your partner(s) have had any fertility treatments.

You will not be removed from the study unless you request to be removed as outlined below.

***Can I stop being in the study?***

Yes. You can decide to stop participating in the study at any time. Tell the study doctor if you are thinking about withdrawing from the study. This disposition of the 75% portion of your tissue that was stored for your future use is your decision (See options on page 8). The 25% portion of your tissue that was originally designated for research cannot be recovered and will not be destroyed.

***What are the possible risks, side effects, and discomforts of this research study?***

Taking part in this study may involve the following risks**:**

**Cryopreservation (freezing):** Although care was taken when your tissues/cells were frozen, unexpected damage to your testicular tissues/cells may have occurred during any part of the cryopreservation (freezing) and storage process. The effects of cryopreservation and storage on human testicular tissues are not known and possible genetic damage to the tissue may occur. However, thousands of children have been born worldwide from frozen embryos and there only isolated reports of minor increased risk of some specific birth defects in these children (e.g., Angelman syndrome, Prader-Willi syndrome, Beckwith-Wiedeman syndrome). The potential risk of genetic mutations that could contribute to birth defects is not a risk to you, but to any child who may be born following any experimental procedures to restore your fertility. You will not be at direct risk of genetic mutation by continuing to participate in this study.

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

**Breach of confidentiality:** Participation in this study does involve the possible risk that information about your health might become known to individuals outside of those directly involved with this study. Any information about you obtained from this research will be kept as confidential (private) as possible (i.e., paper records will be stored in a locked file cabinet and electronic records will be stored in a secure database). Furthermore, your identity on these records will be indicated by a case number rather than by your name and the information linking these case numbers with your identity will be kept separate from the research records. However, it is possible that unauthorized individuals could obtain access to your private health information. You will be notified immediately if the confidentiality of your private information is known to have been breached.

***Are there benefits to taking part in the study?***

Your continued participation in this study may advance our understanding of how to successfully freeze and thaw testicular tissue in a manner that permits subsequent use by patients at some point in the future. If tissue was frozen for your own use, we 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 using experimental techniques currently being developed. We hope that you will get personal medical benefit from participation in this study, but we cannot be certain. We expect that the information learned from this study will benefit other patients in the future.

***What if there is new information while I am in this study?***

We will inform you about research developments or advances that may impact how your tissue might be used in the future to achieve fertility. In addition, if any information is learned that might affect your willingness to continue to participate in this research, you will be informed.

*May I refuse to give my permission for the use of my medical information for the purpose of this research study?*

Your permission to use and disclose your medical information for the purpose of this research study is completely up to you. However, if you do not provide your permission, you will not be allowed to continue participating in this study.

***Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?***

You will be responsible for paying a yearly storage charge (~$300 per year) to keep your tissues frozen. Any future use for restoration of your fertility using this tissue will also be your responsibility.

If a portion of your tissue was donated to research, there will be no additional cost to you for allowing its storage. 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 procedures in the future. No compensation will be given to you now or in the future for the use of these samples. You will not have any control over the storage or use of your testicular tissue donated to research.

The portion of your tissue that was dedicated for your use will remain under your control and expenses associated with any future use of that tissue will be paid by you or your health insurance carrier. 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.

***Will I be paid for participation in this research study?***

You will not receive payment or money for taking part in this study.

***Who will know about my participation in this research study?***

Any information about you obtained from this research will be kept as confidential (private) as possible. All paper and electronic records related to your involvement in this research study will be stored securely. Access to identifiable information will be limited to the PI and co-investigators of this study. Personnel involved in this study are expected to protect the security and confidentiality of identifiable information. You study team members de-identified your testicular tissue and blood sample and label them with a coded ID number before shipping them to Pittsburgh for processing freezing. No identifying information associated with your tissue will be available to the study team members in Pittsburgh or any other individual site associated with this protocol. Your identifiable medical records will be kept separate from the research records. Only the PI and co-investigators at the site where your surgery will be performed will be able to link the coded ID number with your identifiable medical records.

***Will this research study involve the use or disclosure of my identifiable medical information?***

This research study has and will continue to result in identifiable information that will be placed into your medical records held at the hospital where your surgery was performed and will be maintained as confidential. The nature of the identifiable information resulting from your past participation in this research study that were recorded in your medical record includes: results of infectious disease testing for hepatitis B, hepatitis C, syphilis (RDR), Cytomegalovirus, Human T-Lymphotropic virus, Chlamydia, Gonorrhea, West Nile Virus, and Human Immunodeficiency virus, outcome of surgery to remove your testicular tissue and any complications of the surgery. We also recorded your demographic and health and reproductive history, including, but not limited to: race, ethnicity, type of cancer/diagnosis, previous cancer treatments, reproductive history and previous fertility treatments. The report generated by a pathologist who evaluated your testicular tissue was also included in your medical record.

The information collected at your initial enrollment and yearly when we contacted you in the past and continue to contact you yearly to discuss how you are doing may also be treated as medical information in some cases. This information includes: the current status of your primary disease or condition, any additional treatments you have received (such as other chemotherapies, radiation, or surgery), the dates of any additional therapies, any new diseases or conditions you have been diagnosed with since enrolling in the study, any side-effects of treatments, death, your current marital status, your sexual history, if your partner has become pregnant and had any children, and if you or your partner have had any fertility treatments. Since some of this information is technical in nature, we may ask your physician(s) to provide details of your medical condition pertaining to these specific categories of information.

Your name or material identifying you (except as described above) will not be released without written permission, unless required by law.

***Who will have access to identifiable information related to my participation in this research study?***

In general, research records are kept confidential. Paper records are stored in locked cabinets and electronic records are password protected and secured. There are, however, some disclosures of your research-related medical information that may occur.

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

* Authorized representatives of the Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purposes of monitoring the appropriate conduct of this research study.
* Authorized representatives of the hospital where your surgery was performed or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).
* Authorized representatives of the US Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) may review and/or obtain your identifiable health information for the purpose of monitoring the accuracy of research data and to ensure that the research is being conducted according to the FDA regulations. While the FDA has provided its assurance that it will not release your identifiable medical information to anyone else, but this cannot be guaranteed.
* Authorized representatives of the Reprotech, Ltd., the company with which your testicular tissues/cells designated for your use are stored.
* In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

***For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?***

The investigators will be permitted to use your health information indefinitely or until your written request to withdraw from the study is received.

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of five years after final reporting or publication of a project.

***May I have access to my medical information that results from my participation in this research study?***

Yes, in accordance with the [INSERT YOUR INSTITUTION NAME HERE] Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

***Is my participation in this research study voluntary?***

Yes, your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. However, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the [INSERT YOUR INSTITUTION NAME HERE]. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a [INSERT YOUR INSTITUTION NAME] hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your physician may be involved as an investigator in this research study. As both your physician and a research investigator, this doctor is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

***May I withdraw, at a future date, my consent for participation in this research study?***

Yes, you may withdraw your consent for participation in this research study at any time (including the use and disclosure of your identifiable information for the purposes described above). To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the [INSERT YOUR INSTITUTION NAME HERE]. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a [INSERT YOUR INSTITUTION NAME HERE] hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

***What will happen to my frozen tissue if I withdraw, at a future date, my consent for participation in this research study?***

Withdrawal from the study does not mean that you must forfeit your testicular tissue. The decision about what to do with the 75%of testicular tissue that was originally designated for your future use is still yours. If you withdraw from this study, you may choose to:

(1) Continue storing your tissue at your own expense;

(2) Donate all tissue designated for your future use to Magee-Womens Hospital in Pittsburgh for research-use only;

(3) Have the tissue destroyed.

The 25% testicular tissue that was originally designated for research cannot be recovered and will not be destroyed.

Your tissue will only be stored at Magee-Womens Hospital in Pittsburgh for a short time after it is harvested, and then will be shipped to Reprotech, Ltd. The future use of this tissue is governed by the cryostorage agreement you will have to sign with Reprotech, Ltd.

***What will happen to my frozen tissue if I die?***

Disposition of your tissues/cells that are stored at Reprotech, Ltd. are governed by the cryostorage that you and/or your parents signed with Reprotech, Ltd.

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**VOLUNTARY CONSENT**

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, [INSERT YOUR INSTITUTION NAME HERE] (1-INSERT YOUR INSTITUTION PHONE NUMBER).

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Participant’s Printed Name

By signing this form, I give my consent to participate in this research study.

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Participant’s Signature Date

**CERTIFICATION of INFORMED CONSENT**

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual have about this study have been answered and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

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Printed Name of Person Obtaining Consent Role in Research Study

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Signature of Person Obtaining Consent Date