**[INSERT YOUR PEDIATRIC HEMATOLOGY/ONCOLOGY AND BONE MARROW TRANSPLANTATIONCENTER NAME HERE]**

[INSERT Your Treatment Center NAME HERE]

Doctors’ Offices

Phone: xxx-xxx-xxx Phone: xxx-xxx-xxx

Fax: xxx-xxx-xxx Fax: xxx-xxx-xxx

[INSERT YOUR CENTER FOR FERTILITY AND REPRODUCTIVE ENDOCRINOLOGY HERE]

Doctors’ Offices

Phone: xxx-xxx-xxx

Fax: xxx-xxx-xxx

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

**(Consent for Subjects Under 18 years of Age)**

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

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

**CONSENT FOR A CHILD 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 are my child and I being asked to do?***

You are invited to have your child take 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 your child from the study at any time without penalty or loss of any benefits to which he is 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.

Your child is being asked to participate in this research study because he will receive treatment for a medical condition which may result in infertility (inability to have his own children), and you may wish to preserve his testicular tissue for the purpose of possibly allowing him to have his own children in the future. Your son will be undergoing one of the following treatments:

• Surgery, drug treatment, chemotherapy and/or radiation therapy which is expected to result in a loss or impairment of testicular function and/or infertility. Although not all surgery, drug treatment, chemotherapy or radiation treatments affect fertility (the ability to have children), the treatments your child will receive are expected to affect his testicular function and are likely to cause him to become sterile (unable to have children) after therapy is finished.

• Surgery to remove one or both testicles or portions of the testicles as a way of treating or preventing a particular disease, and you may wish to preserve his 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 your son as a potential resource to allow medical procedures to attempt to restore his fertility in the future using experimental techniques currently under development. The study will also provide a portion of your child’s 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.

***What is the current standard of treatment for this problem?***

There is no standard method of preserving fertility in boys who have not undergone puberty (able to produce an ejaculate containing sperm). If your son has gone through puberty, sperm banking will be offered as the first option to preserve his fertility. If he is too sick to bank sperm or does not produce sperm, this protocol will be offered to your son.

***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 will happen on this study that is research?***

If you choose to have your child participate in this study, and are interested in fertility preservation, your child will undergo a surgical procedure to harvest his testicular tissue. Unless this procedure is performed for treatment of your son’s disease or illness, this surgery is considered research. The harvested testicular tissue will be used for pathologic evaluation, a portion will be donated for use in laboratory research, and a portion will be cryopreserved for his later potential use. For this latter portion of your child’s testicular tissue, you will determine how you wish to use his tissue in the future and at which institution until your son is 18 years-old. Once he is 18, your son will be re-consented and he can decide how he wishes to use his tissue in the future and at which institution. After the surgical procedure, there will be one post-operative checkup to make sure your son is healing as expected. There will not be any additional research-related office visits. We will contact you every year by phone or mail until your son has dropped out of the study to follow his medical and fertility status over time, ask questions about any future use of your child’s frozen tissue and the possible outcomes of his fertility preservation treatment.

**RESEARCH PROCEDURES:**

**Pre-Operative Assessment:** Prior to enrollment in the study, your son will be evaluated by his physician to confirm he is eligible for this study. He will also be evaluated by an anesthesiologist. If in the anesthesiologist’s view your child would incur any additional risk of anesthesia by virtue of his disease or his general state of health, then he will not be allowed to continue participating in the study.

**Surgery:** Your child will undergo one of two different surgical procedures to remove testicular tissue. The first is called a wedge resection (removal of a wedge-shaped piece of his testicle) and the second is called an orchiectomy (complete removal of the testicle). The type of surgery and the amount of testicular tissue removed will depend upon your child’s clinical situation and at the discretion of the surgeon. Your son’s surgeon will obtain your full consent for the actual surgical procedure.

The two possible surgeries are:

**Wedge Resection**: A small cut will be made with scalpel in scrotum, a section of the testicle will be removed and the skin will be closed with dissolving sutures (stitches). Alternatively, a small cut will be made in the groin area (subinguinal approach). The testicle will then be pulled up through the inguinal canal (a tunnel running from the abdomen to the scrotum). A section of the testicle will be removed and then the testicle will be placed back in the scrotum in its normal position. The skin will then be closed with dissolving sutures (stitches).

**Simple Orchiectomy**: A small cut will be made with scalpel in scrotum, and the testicle will be removed from the scrotum. The skin will be closed with dissolving sutures (stitches).

The duration of this surgery is likely to be between 60 and 120 minutes. The recovery time required prior to either resuming normal activities or initiating chemotherapy or radiation therapy is expected to be 2-3 days.

The surgical procedure to remove your son’s testicular tissue may be performed solely for research purposes if the procedure itself is not required for the treatment of your son’s disease or condition. If the treatment of his disease or condition requires a different surgery, his medical team will try to coordinate testicular surgery so that it can be performed at the same time. This will help minimize the risks of surgery.

**Laboratory Procedures:** After surgery, a small piece of your son’s testicular tissue (~5%) will be sent to the Department of Pathology and examined under a microscope to determine if it is healthy and free of disease. You will receive a copy of the report of this evaluation. A report that this small piece of testicular tissue appears to be healthy is not a guarantee that the cryopreserved testicular tissue is free of disease (such as cancerous cells), and is known as a “false negative” result. A false negative result means that diseased cells (such as cancer cells) could grow if the cryopreserved tissue is re-implanted in the future.

**Tissue Storage:** The remaining tissue will be shipped to the Testicular Tissue Cryopreservation Coordinating Center at Magee Womens Hospital and processed into small pieces or a suspension of cells for freezing and storage in several separate vials. As a part of this research, a certain percentage (25%) of your son’s tissue will be designated for scientific experiments. For instance, one or more of the vials will 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 be studied prior to freezing. The research portion of the tissue will not be used for any studies that involve fertilization of eggs. The tissues/cells donated for research will not be usable by your son, nor will you or he have any control over the use of these tissues/cells donated to research. There is no charge for storage fees for your son’s testicular tissues/cells that are kept for research.

The testicular tissue/cells designated for your son’s future use (75%) will be stored at an accredited long-term storage facility at Reprotech, Ltd. (RTL) (Roseville, MN) ([http://www.reprot.com](http://www.reprot.com/)). You will be asked to sign a separate cryostorage agreement with Reprotech, Ltd. (RTL) that addresses the ownership, storage, shipping and future disposition of the samples stored at Reprotech. You will not be charged for the first year of storage at and initial shipping charges to Reprotech, Ltd. (RTL). After the first year, you will be responsible for the annual storage fee (approximately $300) and any other charges accrued (e.g. shipping to another institution, at your request). Your son’s tissue will only be stored at Magee-Womens Hospital in Pittsburgh for a short period of time following cryopreservation while shipment to Reprotech, Ltd. (RTL) is arranged. You and your son will retain control over his tissues and may utilize them as you and he deem appropriate at the institution that you and he choose in the future.

During the period of time that your son’s remaining testicular tissue is stored, it is possible that technological advancements will progress for thawing stored testicular tissues. If such advances take place and are found to be safe and effective, you may request to thaw your son’s tissue for the purpose of producing sperm. This may include transplantation into his remaining testicle to restore the ability to make sperm in that testis. As part of his participation in this study, you and he will be updated on new options that are available for the use of his tissue and where those options are available. We cannot give you or him any information about the tissue that you donated to research since it will be de-identified (will not have his name attached to it).

**Amount of tissue donated to Research**. Since this is a research study, some of your son’s tissue will be used to perform scientific experiments to help understand how to best use tissue from patients like him in the future. For this study, after a portion of your son’s testicular tissue is removed for pathological examination (~ 5%). Approximately 25% of the remaining tissue/cells will be de-identified and donated to research. The remaining 75% will be designated for your son’s future use.

**Infectious Disease Testing:** Banking and subsequent use of your son’s 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 child’s tissues are in storage, he will be tested and screened for a number of infectious diseases prior to banking his tissue. These include hepatitis B, hepatitis C, syphilis (RDR), cytomegalovirus (CMV) Human T-lymphotropic virus (HTLV), Chlamydia, Gonorrhea, West Nile Virus, and Human immunodeficiency virus (HIV). For the HIV testing, a separate, standard consent form will be used as with other patients in accordance with state and 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 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 him or would be suitable for use in another individual (such as a gestational carrier/surrogate) in the future, if his medical diagnosis indicates that this is necessary. A gestational surrogate/carrier is another person (i.e., a third-party) who becomes pregnant by transfer of embryos of which she is not the biological mother (i.e., not from her own eggs). In the future, if your son’s partner is unable to carry a pregnancy it is possible that he and his partner may need to identify a woman who would serve as a gestational surrogate/carrier to complete a pregnancy with embryos derived from your son’s cryopreserved material. His tissue will be stored with tissue of the same infectious disease status. This infectious disease testing is only required because tissue is being stored for your son’s use and not because he is donating tissue for research. For this testing, your son will have 24 ml (5 teaspoons) of blood drawn at the time of surgery. 18 ml (4 teaspoons) of your child’s blood will be sent to Memorial Blood Centers for infectious disease testing. The remaining 6 ml (1 teaspoon) will be frozen and stored with your child’s testicular tissue to permit any future testing required under federal tissue banking regulations. In spite of storing blood plasma, it is still possible that federal regulations may change, and therefore, it may not be possible to perform the appropriate testing to permit use of their tissue in the future.

***How long is my child in the study?***

After your son’s tissue is cryopreserved, we will collect personal and medical information about how he is doing each year for as long as he continues to participate in this study (until his written request to withdraw from the study has been received). There is no defined end-point of this study. Once your son is 18 years-old, he will need to consent on his own behalf to continue to participate in this study. Each year we will ask you and/or your son for the following information: the current status of his primary disease or condition, any additional treatments he has received (such as other chemotherapies, radiation, or surgery), the dates of any additional therapies, any new diseases or conditions he has been diagnosed with since enrolling in the study, any side-effects of treatments, death, his current marital status, his sexual history (adolescents and adults), if his sexual partner has become pregnant and had any children (adolescents and adults), and if he and his partner have had any fertility treatments (adolescents and adults). Prior to surgery, it is possible that the study doctor may remove your son from the study if there is a contraindication to surgery. Once tissue is harvested your son will not be removed from the study.

***Can my child 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 having your child withdraw from the study. The disposition of the 75% portion of your child’s tissue that was stored for his future use is your decision (See options on page 13). The 25% portion of your child’s 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:

**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 child’s surgery, if his surgeon or the pathologist (the physician who examines your tissue through the microscope) determines that all of the tissue is needed to diagnose his disease, then no tissue may be available for freezing. If that occurs, your child will not have any testicular tissue frozen for future use.

**Elective (By Choice) Removal of Testicular Tissue:** Your child has been invited to participate in this study because we expect that the treatment or surgery that he will undergo to treat his medical condition or cancer will significantly affect his future fertility. You should also know that it is possible to experience decreased fertility due to the removal of a testicle. Although we do not expect it, he may regain spontaneous testicular function in spite of his medical treatments. If so, then the surgery to remove testicular tissue would have been unnecessary.

**Removal of the entire testicle (simple orchiectomy):** The surgical site may be sore for several days after the surgery. As in all surgical procedures, there is a small risk of post-operative infection. There is less than a 1 in 25 (3.5%) risk of post-operative wound infection. If this occurs, your child’s physicians will treat the infection with the appropriate antibiotics. There is also a 1 in 20 (5%) risk of postoperative bleeding. The chance of your child requiring an extended hospitalization or more extensive surgery for the management of complications is about 1 in 1000 (0.1%). Such complication(s) may necessitate a delay in further chemotherapy or radiation therapy treatments for his disease. Your child’s chance of dying as a result of such complication(s) is less than 1 in 10,000 (0.01%). The risk of minor complications, such as temporary pain or bruising at the incision sites, is 1% (around 1 in 100). Removal of one testicle can also lead to temporary reduction in production of the hormone testosterone, 90-95% of which is produced by the testicles (the balance is produced by the adrenal glands). Depending on whether your son has entered puberty, he may or may not be producing testosterone. If your son has begun puberty, reduced testosterone levels may cause reduced sexual desire, impotence, hot flashes similar to those in menopausal women, mood swings or depression, enlargement and tenderness in the breasts, weight gain, osteoporosis, and fatigue. Testosterone (and other hormone) production will be monitored by your son’s physician as a part of the standard care he will receive after undergoing a treatment that may cause his infertility. As a part of this standard care, hormone replacement will be given as needed. There are also potential psychological consequences of removing a testicle. To address these psychological issues some young men opt to have a testicular prosthesis, or artificial testicle, placed inside the scrotum to replace the testicle removed during surgery. The prosthesis makes the scrotum look much as it did before surgery. If you desire a testicular prosthesis, one can be inserted into the scrotum during the surgery and you should discuss this possibility with your son’s physician.

**Wedge resection of part of the testicle:**

The surgical site may be sore for several days after the surgery. As in all surgical procedures, there is a small risk of post-operative infection. There is less than a 1 in 25 (3.5%) risk of post-operative wound infection. If this occurs, your child’s physicians will treat the infection with the appropriate antibiotics. There is also a 1 in 50 (2%) risk of postoperative bleeding. As opposed to removal of an entire testicle, there will be minimal hormonal side effects or need for a prosthetic testicle as stated above. In addition, it is possible that the surgery itself could cause scar tissue or damage to the remaining testicular tissue, so that chances for producing sperm from that testicle in the future could be reduced, but the risk of this complication is unknown.

**General Anesthesia:** Minor complications of anesthesia, such as sore throat or short-term nausea, are quite common. Your child’s chance of dying from the anesthesia is less than 1 in 10,000. He may already be undergoing general anesthesia for another surgical procedure.

**Cryopreservation (freezing):** Although care will be taken, unexpected damage to the testicular tissues removed from your child may occur 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 are 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 your child, but to any child who may be born following any experimental procedures to restore your son’s fertility. Your son will not be at direct risk of genetic mutation during participation in this study.

**Underlying disease:** Some subjects may have particular risks associated with their underlying disease. If a cancer or other disease already affects the testicular tissue, then it may never be possible to use the tissue in the future. This may not be known until after your child is healthy and wishes to use his stored testicular tissue.

**Catastrophe:** Tissue could be lost or made unusable due to problems with transportation or shipping, 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 child’s surgery may be inadequate to permit safe use of his tissue after the long-term storage. While a sample of his 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 testing may reveal an infection or disease of which you were previously unaware and which may require treatment.

**Emotional Risks:** Your child’s participation in this study may subject him to additional emotional risks beyond those directly related to his planned treatment.

**Breach of confidentiality:** Participation in this study does involve the possible risk that information about your son’s health might become known to individuals outside of those directly involved with this study. Any information about your son 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 son’s identity on these records will be indicated by a case number rather than by his name and the information linking these case numbers with his identity will be kept separate from the research records. However, it is possible that unauthorized individuals could obtain access to your son’s private health information. You will be notified immediately if the confidentiality of your son’s private information is known to have been breached.

***Are There Benefits To Taking Part In The Study?***

Your child’s participation 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 is frozen for your child’s own use, we may have a means to restore his fertility in the future using experimental techniques currently being developed. However, there is a significant possibility that there may be no direct benefit to your child from his participation in this research study. We hope that your child will get personal medical benefit from participation in this clinical trial, but we cannot be certain. We expect that the information learned from this study will benefit other patients in the future.

***What alternatives are available to me if I don’t give my permission for my child’s participation in this study?***

There are no standard procedures for fertility preservation for children about to undergo potentially sterilizing treatment except for sperm banking for adolescent and adult males.

***What if there is new information while my child is in this study?***

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

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

Your permission to use and disclose your child’s medical information for the purpose of this research study is completely up to you. However, if you do not provide your permission, your child will not be allowed to participate 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 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 son’s condition (charges that are not solely for research). How much you have to pay depends on whether or not you have health insurance and what costs your insurer will cover. Any deductible, co-insurances or co-payments that are a part of your insurance coverage will apply. If you have any questions concerning your insurance coverage, you should speak to your healthcare insurance carrier.

If the testicular surgery is being performed as a part of the treatment or prevention of your son’s condition or solely for preservation of fertility, you or your insurance company will be responsible for those charges. Same centers may provide financial assistance to help defray these costs, but this is not guaranteed by this protocol. A member of the study team will discuss these expenses with you.

There will be no charge to you or your insurance provider for research laboratory fees for processing the testicular tissue and cryopreservation (which includes the first year of storage). These are research costs and will not be your responsibility. After the first year, you will be responsible for paying a yearly storage charge (~$300 per year). Any future use for restoration of your son’s fertility using this tissue will also be your/his responsibility.

The research portion of your son’s tissue will be used only for research and will not be sold. The research done with his tissue may lead to the development of new procedures in the future. No compensation will be given to you or your son now or in the future for the use of these samples. Neither you nor your son will have any control over the storage or use of his testicular tissue donated to research.

The portion of your son’s tissue that is for his own use will remain under your control and expenses associated with any future use of that tissue will be paid by you, he or your health insurance carrier. As part of his participation in this study, you and your son will be updated on new options that available for the use of his tissue and where those options are available.

***What if I want my child’s testicular tissue frozen for his use and do not want to donate any portion to research?***

There is no option for freezing your child’s testicular tissue without providing a portion to the research effort.

***Will my child be paid for participation in this research study?***

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

***Who will pay if my child is injured as a result of taking part in this study?***

If you believe that the research procedures have resulted in an injury to your child, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your child’s participation in this research study will be provided to your child by the hospitals of [INSERT YOUR INSTITUTION NAME HERE]. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your child’s research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

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

Any information about your child 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 will de-identify your son’s testicular 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 sons tissue will be available to the study team members in Pittsburgh or any other individual site associated with this protocol. Your child’s identifiable medical records will be kept separate from the research records. Only the PI and co-investigators at the site where your child’s surgery will be performed will be able to link the coded ID number with your child’s identifiable medical records.

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

This research study will result in identifiable information that will be placed into your child’s medical records held at [INSERT YOUR INSTITUTION NAME HERE] and will be maintained as confidential research records. The nature of the identifiable information resulting from your child’s participation in this research study that will be recorded in your child’s 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 and outcome of surgery to remove your son’s testicular tissue and any complications of the surgery. We will also record your son’s 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 evaluates your son’s testicular tissue will also be included in your son’s medical record.

The information collected at your son’s initial enrollment and yearly when we contact you and your son to discuss how he is doing may also be treated as medical information in some cases. This information includes: the current status of his primary disease or condition, any additional treatments he has received (such as other chemotherapies, radiation, or surgery), the dates of any additional therapies, any new diseases or conditions he has been diagnosed with since enrolling in the study, any side-effects of treatments, death, his current marital status, his sexual history (adolescents and adults), if his sexual partner has become pregnant and had any children (adolescents and adults), and if he and his partner have had any fertility treatments (adolescents and adults). 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.

Results of some non-FDA approved research tests may also be communicated to your son’s physician and could be included as a notation in his medical record.

Your son’s name or material identifying your son (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 child’s 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 child’s 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 child’s identifiable medical information) related to your child’s participation in this research study:

• Authorized representatives of the Research Conduct and Compliance Office may review your child’s identifiable research information (which may include your child’s identifiable medical information) for the purposes of monitoring the appropriate conduct of this research study.

• Authorized representatives of the hospital where your child’s surgery was performed or other affiliated health care providers may have access to identifiable information (which may include your child’s identifiable medical information) related to your child’s 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 child’s 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 child’s identifiable medical information to anyone else, this cannot be guaranteed.

• Authorized representatives of Reprotech, Ltd., the company with whom you will agree to store your son’s testicular tissues/cells that are designated for his future use.

• In unusual cases, the investigators may be required to release identifiable information (which may include your child’s identifiable medical information) related to your child’s participation in this research study in response to an order from a court of law. If the investigators learn that you, your child 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 child’s participation in this research study?***

The investigators will be permitted to use your child’s 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 child’s identifiable medical information) related to his 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 child’s 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 child’s participation in this research study) contained within your child’s medical records filed with his health care provider.

***Is my child’s participation in this research study voluntary?***

Yes, your child’s participation in this research study, to include the use and disclosure of your child’s identifiable information for the purposes described above, is completely voluntary. However, if you do not provide your consent for the use and disclosure of your child’s identifiable information for the purposes described above, you will not be allowed, in general, to have your child participate in the research study. Whether or not you provide your consent for your child’s 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 your child’s 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.

Your child’s physician may be involved as an investigator in this research study. As both your child’s physician and a research investigator, this doctor is interested both in your son’s 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 child’s care with another doctor who is not associated with this research study. Your child is not under any obligation to participate in any research study offered by his doctor.

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

Yes, you may withdraw your consent, for your child’s participation in this research study at any time (including the use and disclosure of your child’s identifiable information for the purposes described above). To formally withdraw your consent for your child’s 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 your child’s participation in this research study will have no effect on you or your child’s current or future relationship with the [INSERT YOUR INSTITUTION NAME HERE]. Your decision to withdraw your consent for your child’s participation in this research study will have no effect on your child’s current or future medical care at a [INSERT YOUR INSTITUTION NAME HERE] hospital or affiliated health care provider or your child’s current or future relationship with a health care insurance provider.

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

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

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

(2) Donate all tissue designated for his 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.

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

***What will happen to my child’s frozen tissue if he dies?***

If your child dies while his tissue is stored at Magee-Womens Hospital in Pittsburgh, all tissue frozen for his future use will either be donated exclusively for research or destroyed. Please initial next to the statement that matches your wishes and draw lines through the other statement.

\_\_\_\_\_\_\_ I wish to donate all of my child’s stored testicular tissue to research in the event of his death.

 \_\_\_\_\_\_\_ I do not wish to donate any of my child’s stored testicular tissue to research in the event of his death and it will be destroyed. I understand that tissue already designated for research will be maintained for future laboratory research and will not be destroyed.

After your son’s tissues/cells are shipped to Reprotech, Ltd. the future use of that tissue will be governed by the cryostorage agreement that you sign with Reprotech.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

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 child’s 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 HERE).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s (Child’s) Printed Name

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his participation in this research study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent’s Name (Print) Relationship to Participant (Child)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent’s Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent’s Name (Print) Relationship to Participant (Child)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent’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(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) 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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent Role in Research Study

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

**ASSENT (For children who are not capable of understanding the study procedures and their potential discomforts and benefits).**

I do not believe the child/my child is capable of giving assent for participation.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature(s) of Parents(s) Date

**ASSENT (For children who are capable of understanding the study procedures and their potential discomforts and benefits).**

I have explained this research to the child-subject in words and pictures that he understands, and I believe he understands what this research involves.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Person Explaining the Research Date

The research procedures have been explained to me in a way that I understand and I understand the potential discomforts and benefits of participating in this study. By signing this form, I give my assent to participate in this research study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Child Date

**VERIFICATION OF EXPLANATION**

I certify that I have carefully explained the purpose and nature of this research to (name of child) in age appropriate language. He has had an opportunity to discuss it with me in detail. I have answered all his questions and he provided affirmative agreement (i.e., assent) to participate in this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal/Co-Investigator Signature Date