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

 **Doctors’ Offices**

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

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

**[YOUR Center for Fertility and Reproductive Endocrinology]**

Phone: xxx-xxx-xxx

Fax: xxx-xxx-xxx

TITLE: Testicular tissue cryopreservation for fertility preservation in patients facing an infertility-causing disease or treatment regimens

**(HIV 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]

**DESCRIPTION:**

You have been asked to allow your child to participate in a research study which will involve testing his or her blood for HIV antibodies**.**

**PURPOSE, MEANING, AND LIMITATIONS:**

You agree to allow about 2 teaspoons of blood to be drawn from a vein in your child’s arm. This sample will be tested for the antibody to the human immunodeficiency virus (also known as HIV). An antibody is a substance that blood cells make to fight infection. A positive HIV test means that your child’s blood sample tested positive for HIV and that repeat testing will be performed to confirm (prove) this finding. If your child’s sample is proved to be positive for HIV, it means that he or she is a carrier of HIV. It also means that he or she could pass the virus to others by intimate sexual contact, by sharing needles, and through donating blood and organs. A negative HIV test means that at this time, no antibody to HIV was found in your child’s blood sample based on the result of the initial screening test, repeat screening tests, or a confirmatory test.

There can be individuals who have HIV test results that are called “false positive,” which means that for some reason, the test indicates that HIV antibodies are present in the blood when they are not. There can also be “false negative” results which can have two possible meanings; 1) the person has been infected with HIV, but that person’s body has not yet made antibodies to the virus, or 2) the HIV antibody is present in the person’s blood, but for some reason the test failed to detect it.

You will be contacted when your child’s test results are complete to schedule an appointment to learn your child’s HIV results.

If your child tests positive for the HIV antibody, you will be asked to allow an additional 2 teaspoons of blood to be drawn from a vein in your child’s arm for a confirmatory HIV test. You and your child will also be counseled about the risks for transmitting HIV to others, risks for developing AIDS, and the available treatments for HIV infection. You will return to the clinic to receive the results from this repeat test, but will no longer be tested in the clinic for HIV antibody. Your child will be referred, if desired, for proper medical care.

**RISKS AND BENEFITS:**

The benefits of participating in this study are that your child will be tested for HIV infection and counseled regarding HIV infection at no cost to you. You will be given the results of these tests and referred for proper medical care, if needed and desired. The risks of participating are minimal. They include the discomfort of drawing a sample of blood, rare bruising and infection at the site of needle stick, and very rarely, fainting. There may be emotional discomfort or stress associated with the waiting period before test results are given, or due to knowledge of the actual final test results.

**COSTS AND PAYMENTS:**

There will be no costs for participating in this testing and the associated counseling. The blood tests will be free of charge. Also, you understand that you will receive no payment.

**CONFIDENTIALITY:**

You understand that your child’s name is not recorded anywhere in the files for this study. Consequently, you understand that any information obtained from this testing will be anonymous and be stored in locked files. Your child will not be identified in any publication. You understand that all information will be handled in compliance with the Pennsylvania law on HIV-related confidential information. In unusual circumstances, you understand that your child’s research records may be inspected by appropriate government agencies or be released in response to an order from a court of competent jurisdiction, but the records do not contain your child’s name or identification.

**RIGHT TO REFUSE:**

You understand that your child does not have to take part in this testing. However, once your child has the test performed you understand that it is a requirement that you and your child be informed of the results. You understand that counseling is available to you and your child before you make the decision to participate in this testing.

**COMPENSATION FOR ILLNESS OR INJURY:**

[INSERT YOUR INSTITUTION NAME HERE] researchers and their associates who provide services at [INSERT YOUR INSTITUTION NAME HERE] recognize the importance of your child’s voluntary participation in research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that your child is injured as a result of the research procedures being performed, please contact immediately the Principal Investigator or one of the co-investigators 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]. It is possible that [INSERT YOUR INSTITUTION NAME HERE] may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

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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 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).

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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 her participation in this research study.

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

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Parent’s Signature Date

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

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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.

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Printed Name of Person Obtaining Consent Role in Research Study

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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.

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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 she understands, and I believe she understands what this research involves.

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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.

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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. She has had an opportunity to discuss it with me in detail. I have answered all her questions and she provided affirmative agreement (i.e., assent) to participate in this research.

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Principal/Co-Investigator Signature Date