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Informed Consent and HIPAA Authorization To Permit The Use And Disclosure Of Health Information (Protected Health Information) For Research Purposes

Medical Title: Does a History of Cancer Affect a Subsequent Pregnancy or Long Term Maternal Health?

Lay Title: Pregnancy and Cancer: A computer registry collecting information on mother and child's outcome.

Department: Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology

Principal Investigator: Elyce Cardonick, MD **Telephone**: 856-342-2491

Participant's Name: _____

Participant's Address: _____

Date of Birth: _____

What Is an Informed Consent?

You are being asked to take part in a clinical research study. Before you can make an informed decision whether to participate, you should understand the possible risks and benefits associated with this study. This process in known as *informed consent* and means that you will:

- Receive detailed information about this research study;
- Be asked to read, sign and date this informed consent, once you understand the study and wish to participate. If you don't understand something about the study or if you have questions, please be sure to ask for an explanation before you sign this form.
- Be given a copy of this signed and dated form to keep for your own records.

Be aware that your relationship with the research physician bears certain differences from your relationship with your personal physician. Your personal physician individualizes the treatment of your specific problem with the expectation of a benefit to you. The research physician treats all subjects under a specific protocol to obtain generalizable knowledge and on the premise that you may or may not benefit from your participation in the study. Be sure to ask questions of the study physician if you want further clarification of this relationship.

What is HIPAA? Why are you being asked to sign this form?

The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives subjects in research studies certain rights about their protected health information. Protected health information is information about a person's physical or mental health that can be identified with or linked to that particular person. As a subject in a research study, you have the right to know what health information will be used and created about you, how this information will be used, and who will be able to see the information. You also have the right to see your own health information. If you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your health information for this research study.

Introduction and Study Purpose

Treatments for childhood or adolescent cancers have improved the survival for many women to and beyond the reproductive years. Also, with newer treatments most women continue to menstruate regularly after chemotherapy is completed. For these reasons, women considering pregnancy can have a prior history of cancer treatment. Patients are concerned about the effects of prior treatment on their children. A patient's perception of her quality of life after cancer can change with different life events. How a pregnancy may affect one's quality of life is not known.

Research procedure, including what information will be collected from you for use in this study?

If you decide to be in this study, new health information will be created about you. The following information will be sought:

1. The details about the diagnosis and treatment of your cancer including any surgery, radiation, and chemotherapy agents used will be obtained from your oncologist's records. In addition, you will be asked about any family history of cancer or birth defects.

2. The outcome of the pregnancy: the neonate's birthweight, gender, Apgar scores, and the physical impression of the pediatrician regarding the presence of any birth defects.

All of this information would have been gathered/evaluated even if you were not in this research study, but for this study this information will be collected from patient's with a history of cancer before pregnancy to gain experience on the pregnancy outcomes of women with cancer.

3. To determine if any problems that may occur in your pregnancy are related to other factors besides cancer and prior cancer therapy, medical records regarding past pregnancies will be evaluated when prenatal records are requested from the obstetrician. This will also include information about any medical conditions, and medications to treat these conditions, outside of pregnancy.

4. If patients had received radiation as part of cancer treatment, the placenta at delivery will be sent for examination by a pathologist at the institution where the patient received obstetrical care.

5. For follow up, yearly questionnaires will be sent to each patient's oncologist and the child's pediatrician. These will ask for information on the status of cancer since pregnancy for the patient, and the health of children born to cancer survivors with regards to meeting expected milestones in development and growth.

Again, this information would have been evaluated by the oncologist of the patient, and the pediatrician of each child even if you were not in this research study, but the evaluations will be collected to evaluate the health status of cancer survivors who have children after cancer.
I need not answer any questions I may find inappropriate or disturbing.

Benefits to Subject
I will not benefit directly from my participation in this study. However, the information gathered from me and many others like me may provide valuable knowledge so that patients who survive cancer and want to have a family may be better advised. Benefits from my participation may include my ability to contact other woman with a history of cancer who are pregnant.

Risks/Discomforts
Potential risks include possible stress when answering questions regarding my disease state and pregnancy outcome. I understand that since the researchers will only observe my medical condition and not participate in my care there is no risk of physical injury as a direct result of this study.

Confidentiality
Care will be taken to preserve the confidentiality of all information and I understand that a record of my progress while on this study will be kept in a confidential form at Cooper Hospital. The confidentiality of my computer record in the database will be carefully guarded and no information by which I can be identified will be released or published. My study records, including conversations that I will have with individuals at Cooper, may be subject to review by the appropriate offices of Cooper Hospital, and my insurance carrier, if necessary.
The new information will be placed into research study files and medical records. These files and records will be stored at the principal investigator's office at Robert Wood Johnson, Camden Campus, part of the Cooper Health System.

How will your health information be used and disclosed?
The information described above will be used to review your health history, including the cancer diagnosis and treatment. Information about the neonate's birth weight, physical exam and apgar scores will help investigators learn if cancer survivors who desire children can continue to be reassured about the ability to have healthy children, yet at the same time observe if there are any trends or differences with regards to specific cancer types, or treatments.

In addition to the investigators listed on the first page of this form and their research staff, other people in the Cooper Health System (CHS) will be able to see your health information (described above) related to this research study: The other people are described below.

There is an Institutional Review Board (IRB) that oversees research in the CHS. People who represent this IRB may review your health information because they need to see how the study is going.

People outside the CHS from the agencies described below will also be able to see your health information under certain circumstances. **These other people outside the CHS understand how important it is to keep your health information confidential. However, the CHS cannot guarantee that your information will be kept confidential after it has been given to people**

outside the CHS. The federal privacy rules do *not* cover any disclosures of your health information by these other people and agencies described below.

A federal agency called the Office of Human Research Protection (OHRP) oversees the CHS IRB. People from OHRP may also review your health information because they need to see how the IRB is doing.

People who work for the U.S. Food and Drug Administration (FDA) may see and/or receive copies of your health information. They need to make sure the research data are accurate. They also need to be sure that the investigators, research staff, and the CHS IRB are following FDA regulations.

Compensation in the Case of Injury
I also understand that, in the event of physical injury or illness resulting to (me)/(my child) as a direct result of the experiments, treatment(s), and/or procedure(s) used in this investigation, comprehensive medical and/or surgical care (including hospitalization) to the extent needed and available will be provided. However, Cooper Hospital cannot assure that this comprehensive medical and/or surgical care will be provided without charge, and I understand that the costs incurred for this care may ultimately be my responsibility.

If you believe that you have been injured or become ill because you took part in this study, you should call the Chief Medical Officer or his representative at (856-968-7858).

Payment I <u>will not</u> receive payment for my participation in this study.

Significant New Findings
As the research progresses, any significant new finding(s), beneficial or otherwise, will be told to me and explained as it relates to the course of my treatment.

Costs
There is no cost to you for participation in this study.

Will you have access to your health information resulting from participation in this research study?

You may already have a copy of CHS's Notice of Privacy Practices. If you do not have one, the investigator will give you one. This notice says that you are allowed to see information that is in your research study records and medical records that are filed in the offices of your health care provider. For this research study that means the office of the investigators and Cooper Hospital. However, you may not see your health information until the study is finished. You have the right to see information that was created as a result of your participation in this study and information that was collected and used for this research study. If you want to see this information, contact Dr. Elyce Cardonick, 856-342-2491.

How long will the investigators be allowed to use your health information?

The investigators may continue to use and disclose your health information for the purposes described above for an undetermined period of time. If you sign this form, you authorize the use and disclosure of your information for this study at any time in the future.

Individuals to Contact
If you have questions or concerns about this research, you are free to ask questions about these procedures to the Principal Investigator, Dr. Elyce Cardonick at telephone: 856-342-2491.

You should call the Chief Medical Officer or his representative at (856-968-7858) (a) if you have any questions about your rights as a research subject or your rights related to the research use of your PHI, (b) if you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) if you believe that you are being forced to stay in this study when you do not want to, or (d) you have any complaints about the research.

May you refuse to give your authorization (permission) for the use of your health information for the purpose of this research study?
Participation in this research study is voluntary. Refusal to participate in this research study will not prejudice your further care. If you decide to participate, you may discontinue participation in the study at any time without prejudice to your further care.

You do not have to give your authorization to use and disclose your health information as described above. Your authorization is completely voluntary. However, if you do not give your written authorization for the investigators to use and disclosure your health information, you may not be in the research study.

Alternative Treatments
Your alternative is not to participate in this study. Should you choose not to participate in this study, there is no penalty. It will not affect your care at CHS, its affiliated health care providers, or hospitals now or in the future.

Subject Withdrawal
You may decide at any time that you no longer want the investigators to use and disclose your health information. In that case, you will not be able to continue in this research study. The investigator and research staff will stop collecting health information from you for this study. In addition, research staff will stop using your health information. The research staff may have relied on information that has already been collected from you. For example, the study staff may need to use or disclose information that they got before you withdrew your authorization in order to keep the scientific integrity of the study. The investigator also may have to use or disclose your health information to the FDA to explain why you withdrew from the study.

You may withdraw my consent and discontinue participation in this study without penalty and without affecting my future care or my ability to receive alternative medical treatment at Cooper Health System. You may also decide to give consent for the investigator to continue to collect your health information after you withdraw from the study.

If you decide to withdraw your authorization, you should give a written and dated notice of your decision to the principal investigator at 1 Cooper Plaza, Dorrance Building, suite 623. This decision will not affect your care at CHS, its affiliated health care providers, or hospitals now or in the future.

Voluntary Consent

I voluntarily consent to participate in this research investigation. I understand what my participation will involve, including the possible risks and benefits of my participation.

I agree to sign this form and allow access to my medical records and those of my newborn for review. I give permission for me, my family, my oncologist, and my child's pediatrician to be contacted by phone or mail yearly.

My Name *(please print):*_____Signature:_____

Date:_____Time:_____

Witness Signature_____Date:_____

To the best of my knowledge, the subject _____, has assimilated the entire content of the above consent form. Any questions asked have been answered to her complete satisfaction.

Investigator:_____Signature: _____

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HIPPA AUTHORIZATION

VOLUNTARY CONSENT

HIPAA: AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF HEALTH INFORMATION (PROTECTED HEALTH INFORMATION) FOR RESEARCH PURPOSES

All of the above has been explained to me. All of my questions have been answered. I am free to ask any questions I have about the research use and disclosure of my health information at any time. My questions will be answered by one of the investigators listed on the first page of this form.

If I have any questions about my rights related to the use of my health information for research, I should call the Chief Medical Officer or his representative at (856-968-7858).

By signing this form, I agree to allow the use and disclosure of my health information for the purposes described above. A copy of this authorization form will be given to me.

_____ _____

Subject's Signature Date