Cooper University Hospital

INFORMED CONSENT and HIPAA AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES

Medical Title: *Maternal Cancer Diagnosis and Treatment during Pregnancy: Longitudinal Follow-Up of Child Development and Maternal Survivorship.*

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

Sponsor: Cooper University Hospital

Funder: Cooper Foundation

Principal Investigator: Elyce Cardonick, MD **Telephone**: 856-342-2491
856-757-7876

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 do not understand something about the study or have questions, please be sure to ask for an explanation before signing this form.
- Be given a copy of this signed and dated form to keep for personal 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.

Introduction, Background and Study Purpose
As women delay pregnancy to older maternal age, the occurrence of cancer is becoming more frequent during pregnancy. For example, seven to fifteen percent of breast cancer cases occur in

pregnant women making it the most common cancer diagnosed during pregnancy. The medical literature currently cannot answer all the relevant questions for the woman facing this cancer or other types during pregnancy. Few oncologists or obstetricians treat more then 1 or 2 patients in this situation in an entire career. The only way to gain the necessary knowledge about cancer found and treated during pregnancy is to gather together experience from various hospitals into one single database. A physician at Cooper is carrying out a research study to determine the effects of a newly diagnosed cancer and cancer treatment on a concurrent pregnancy. In addition, the current medical literature provides little information on the long term follow up of the children of women diagnosed with cancer during pregnancy.

To date, there is no objective assessment of side effects for women receiving during pregnancy, but many women in the Registry anecdotally tell us that their symptoms are milder than they expect them to be. You will be asked to complete two quality of life questionnaires during cycles 1, 2 and 3 during pregnancy and one additional cycle postpartum if you have the same type of chemotherapy as during pregnancy.

Procedures/Treatment: What information will be collected for use in this study?
This protocol involves two major areas of focus: you and your child. Your oncologist and child's pediatrician can provide yearly follow up on the physical health of you and your child.
If you decide to be in this study, the following health information will be collected:

Medical records will be requested from the oncologist and obstetrician. Information collected will be regarding your general health status prior to the diagnosis of cancer, and information on how cancer was diagnosed during pregnancy. Throughout pregnancy and postpartum period, information will be requested on the progress of cancer treatment suggested and administered by the oncologist. This may include details about clinically significant blood test results, treatment, surgery, chemotherapy agents and doses. Prenatal records will include information about any family history of cancer, other medical illnesses or family history of birth defects.

No alteration of standard oncology or prenatal care will be suggested. The outcome of the pregnancy will be sought, including the neonate's birthweight, gender, Apgar scores, results of newborn hearing screen and the physical impression of the pediatrician regarding the presence of any birth defects. Placental evaluation and blood count from the umbilical cord by your obstetrician will be collected at delivery by your obstetrician.

The Cooper research team will study the slides from the placenta that your obstetrician already collected and examine them to compare the appearance between placentas from pregnancies in which chemotherapy was given, and pregnancies which were not exposed to chemotherapy before delivery. We will be sending samples of formalin-fixed paraffin embedded placental blocks to international expert for review without your name or identifying information provided to our collaborators UZ Leuven group of researchers/or INCIP group (International Network on Cancer, Infertility and Pregnancy).

Do you give us permission to obtain slides from the pathology department at your hospital?

0 Yes 0 No _____ Initials

Specifically for purposes of this study, you may be asked to collect samples from your baby's first three stooled diapers to analyze for breakdown products of the chemotherapy drugs you have been treated with. If you are interested in participating in this portion of the study, supplies will be sent to you for the collection and return mailing of the specimens at no charge to you. Please check the box indicating your interest in participating in this portion of the study:

I would be willing to collect samples from my baby's first three stooled diapers for analysis:

0 Yes 0 No Initials

For follow up, yearly questionnaires will be mailed to your oncologist asking for information about the status of cancer since pregnancy. To follow the health of your child, their and pediatrician will also receive at most a yearly questionnaire concerning the meeting of expected milestones in development and growth at the routinely scheduled visits by the pediatrician.

Once your child is at least 18 months of age, you will be mailed a CBCL survey, a questionnaire regarding your child's social emotional development.
CBCL will be mailed to you when your child is older, between 5 and 17 years old.

When your child is at least 18 months of age, you will be offered an opportunity for intelligence testing to be performed by a special developmental pediatrician. See below for the ages at which testing is offered. This involves fun activities for the younger child (i.e., building with blocks, puzzles, coloring, answering questions). For older children the specialist will assess her/his thinking processes, math and reading skills.

This testing is voluntary and your insurance company will not be billed.

Child's Age	**Assessment**
18 months - 3 years	Bayley Scales III
4-7years	WPPSI-R
7+ years	WISC/WIAT

You need not answer any questions which you find inappropriate or disturbing.

New health information files that will be created about you:
The information collected, described in Procedures/Treatment will be placed into your research study files and medical records. These files and records will be stored and locked in the principal investigator's office at the E and R building on the Camden Campus, part of the Cooper University Hospital System.

Benefits
Women participating in the Registry may benefit from the knowledge that other women are experiencing the complicated situation of a cancer diagnosis during pregnancy. Pooling the pregnancy outcomes of many women diagnosed and treated for cancer during pregnancy may benefit women newly diagnosed with cancer during pregnancy who need to make decisions about cancer treatment during pregnancy and have concerns about the impact, if any, on their child being in utero at the time of the cancer diagnosis and treatment. What we learn about how much of the different cancer drugs is in babies' stool may help guide oncologists (cancer doctors) on whether or not to offer these medications in pregnancy. You may still have such concerns in the long term, and a personal benefit to your participation in this study will be the receipt of a standardized assessment of your child's developmental skill levels, and a verbal report on their developmental progress.

Risks/Discomforts
All patient information will be kept confidential. There is no risk of physical injury as a direct result of this study. Most samples are being collected for your regular care. The samples from your baby's stooled diapers do not add to any risk for participation in this study. Potential risks include possible stress when answering questions regarding your cancer diagnosis and pregnancy outcome or the assessments of your child's behavior at different ages. **Confidentiality**
Care will be taken to preserve the confidentiality of all information and you understand that a record of your pregnancy while in this study will be kept in a confidential form at the E and R Building on the campus of Cooper Health System. The confidentiality of any computer record will be carefully guarded and no information by which you can be identified will be released or published. Your study records, including conversations that you will have with individuals at Cooper, may be subject to review by the appropriate offices of Cooper hospital, and your insurance carrier, if necessary. The samples from your baby's diapers (described above) will be sent to a lab at Drexel University to look for any traces of your cancer medications. These samples will be identified with a study number, not your name or your baby's name.

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 what study files will be created from your information, 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 permission to use your health information for this research study and to answer future research questions.

How will your health information be used and disclosed?

The information described above will be used to review your health history, cancer diagnosis, treatment, and the outcome of your pregnancy. The information will not be used to change the plan of care recommended by your oncologist.

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 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. In unusual cases, an order from a court of law may require the investigators to release your health information. This information may include study records and other medical record information. State law may require the investigators to inform the appropriate agencies if the investigators learn that you or someone with whom you are involved is in serious danger or potential harm.

Your information may also be used to inform you about Cooper sponsored activities, including fundraising programs and events. Only limited information will be used for this purpose. You have no obligation to respond to these communications and may choose to discontinue them. To opt out of these communications, please call 1-800-500-0333 and request to opt out of Cooper communications.

In addition, some of your information may be sent to investigators at UZ Leuven, Belgium who participate with Dr. Cardonick in INCEP, the International Network of Cancer, Infertility and Pregnancy, collaborating on studies of cancer diagnosis and treatment during pregnancy. Any information shared with INCEP would first be de-identified (there will be no information that can be used to identify you).

Compensation in the Case of Injury
You also understand that, in the event of physical injury or illness resulting to (you)/(your 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 you understand that the costs incurred for this care may ultimately be your 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 (856-342-3071).
A review by a committee will be arranged to determine if the injury or illness is a direct result of participation in this research. You should also contact that person if you have any questions about your rights as a research subject or if you believe that you have not been adequately informed as to the risks, benefits, alternative procedures, or that you are being pressured to continue in this study against my wishes.

Payment
You will not receive payment for participation in this study.

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

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

Individuals to Contact
If there are any questions or concerns about this research, feel free to ask questions about these procedures and to ask for additional information from the doctor identified on this consent form as the Principal Investigator , his/her designated representative, or any other doctors involved in my care. Contact the Principal Investigator(s), Dr. Elyce Cardonick at Telephone: 856-342-2491.

You should call the Chief Medical Officer or his representative at (856-342-3071) (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. You should also contact that person if you believe that you have not been adequately informed as to the risks, benefits, or alternative procedures of this research study, or that you are being pressured to participate in the study against your wishes.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. The phone number is 856 757-7832.

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 the research study records and medical records that are filed in the

offices of the health care provider. For this research study that means the office of the investigators and Cooper Hospital. However, you may not see the health information until the study is finished. You have the right to see study files that have been 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.

Alternatives
Your alternative is not to participate in this study. Should you choose not to participate in this study, there is no penalty.

Right to Refuse
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 my further care.

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

If you decide not to allow the investigators to use and disclosure your health information for this research study it will not affect your care at CHS, its affiliated health care providers, or hospitals now or in the future.

Right to 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 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. 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 also decide to give consent for the investigator to continue to collect my 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 and I agree to the use and disclosure of my health information for this and for future research analyses. I understand what my participation will involve, including the possible risks and benefits of my participation. I have had adequate time to read this form and I understand its contents. I will be given a copy for my personal records.

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.

I give permission to be contacted by mail when my child is 18 months of age to ask if I am interested in scheduling intelligence testing on my child by a developmental pediatrician. I give permission for behavioral assessment (CBCL) to be mailed to me to voluntarily complete when my child is at least 18 months of age and again after age 5 years.

I understand by signing this form I am not waiving any legal rights to which I might otherwise be entitled.

_____ _____

Name of Subject Signature of Subject

_____ _____

Date Time

I have discussed the study described above with the subject. Any questions have been answered to his/her satisfaction.

_____ _____

Investigator Obtaining Consent (Print Name) Investigator Obtaining Consent (Signature)

_____ _____

Date Time

Cooper IRB Number: 15-028
IRB Approval Date: 03/17/2021
IRB Expiration Date: 04/14/2022