INFORMED CONSENT and HIPAA AUTHORIZATION

Medical Title: Maternal cancer diagnosis and treatment during pregnancy: establishing a database for maternal, fetal, and neonatal outcomes, including after in-utero exposure to chemotherapy. Longitudinal follow up of child development and maternal psychological well being.

Lay Title: Pregnancy and Cancer: A registry collecting information on mother and child's outcome. How are children exposed prenatally to chemotherapy developing as they reach the preschool and early school age years? How does the experience of having cancer during pregnancy affect a woman psychologically (i.e., stress, parenting anxiety) at least 18 months after delivery? At least 18 months after a pregnancy complicated by the diagnosis of cancer, how are mom and child faring?

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

Principal Investigator: Elyce Cardonick, MD
Co-Investigator: Dr. Marci Gringlas
Telephone: 856-342-2491

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 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.

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 permission to use your health information for this research study.

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. Additionally, the interaction of a pregnancy on the natural history of certain types of cancer will also be studied.

Children treated for acute leukemia with certain types of chemotherapy may be at risk for affects on their heart years later. This is rarer nowadays as the doses of chemotherapy given to children and adults is kept below the dosage that was shown in the past to affect one's heart. Effects of cancer therapy on the development and function of the fetal heart, if any, is unknown.

Moreover, information regarding the impact of having a diagnosis of cancer specifically during pregnancy is also limited. Post traumatic stress symptoms for these women, as well as the psychosocial impact of having to make decisions about cancer treatment during pregnancy, may linger as these women raise their children and are concerned about the long term effects of her cancer and the cancer treatment on the child. Looking at the psychosocial well being of this unique group of women has not yet been done.

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 pediatrician can provide yearly follow up physical health of you and your child. After your child is 18 months of age, you will offered additional voluntary studies if you choose to participate. These will involve age appropriate developmental testing (i..e, cognitive assessment and social emotional assessment of your child), and/ or maternal surveys to assess of psychosocial maternal well-being and child rearing practices.

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, information will be requested on the progress of cancer treatment suggested and administered by the oncologist. This may include details about 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 routine prenatal care will be suggested. With the use of certain chemotherapy agents however, obtaining an additional ultrasound of the fetal heart (an echocardiogram) will be recommended. Repeated ultrasounds have not been shown to be harmful to a developing fetus. The echocardiograms will only be performed on fetuses exposed in utero to certain types of chemotherapy, anthracyclines.

The outcome of the pregnancy will be sought, including the neonate's birthweight, gender, Apgar scores, and the physical impression of the pediatrician regarding the presence of any birth defects. Placental evaluation and blood count from the umbilical cord will be collected at delivery if chemotherapy was given during pregnancy.

You may be asked to bring your child for another heart ultrasound after birth.

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 pediatrician will also receive a yearly questionnaire concerning the meeting expected milestones in development and growth at the routinely scheduled visits.

In addition, a specialist known as a developmental pediatrician, Dr. Marci Gringlas, will offer an opportunity for intelligence testing on children in utero at the time of a maternal diagnosis of cancer. See below for the ages at which testing is offered. This mostly involves fun activities for the child (i.e., building with blocks, puzzles, coloring, answering questions). **You may be present during the entire process and will receive the results the same day.**
This testing is voluntary and will be performed at Cooper University Hospital.

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

Simultaneously, you will be asked to complete the Child Behavior Checklist (CBCL), a questionnaire regarding your child's social emotional development, and the Block Child Rearing Practices Report (CRPR) tapping maternal child rearing attitudes, values, and behaviors and goals.

To assess maternal well being you will be asked to complete 2 short surveys.
1. An Impact of Events Scale (IES) which will assess my perception of the experience of being the diagnosed with cancer during pregnancy.
This requires about 5 minutes to complete.
2. A Brief Symptom Inventory (BSI) assesses current psychological adjustment and well being.

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

New health information will be created about you
The new information collected, described in Procedures/Treatment will be placed into your 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.

Benefits
You may not benefit directly from participating in this study in that you have already been treated for cancer during pregnancy. However, there may be a benefit to 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. 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. No patient addresses will be released to other women at any time and no names or phone numbers will be released without permission. There is no risk of physical injury as a direct result of this study. Potential risks include possible stress when answering questions regarding your cancer diagnosis and pregnancy outcome. After completing these surveys if you appear to be having significant distress about the experience of having had cancer during pregnancy, or about your child's development, you will be referred to the Behavioral Medicine Services Department within the Cancer Institute of New Jersey at Cooper University Hospital. There are physicians in this department who have a specific interest in the psychosocial effects of cancer and are specialists treating anxiety and depression.

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 Cooper Hospital. The database is located on a single computer that is not part of a centralized network. 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.

How will your health information be used and disclosed?

The information described above will be used to review your health history, cancer diagnosis and 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.

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 suffered injury or illness due to participation in this study you should notify the Senior Vice President for Academic Affairs or her designee at 856-963-3835. 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 my 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. If there are any questions regarding my rights as a research participant, I may contact the Senior Vice President for Academic Affairs or her designee at 856-963-3835.

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 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

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 my 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 my 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 my 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 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 when my child is 18 months of age by mail to ask if I am interested in scheduling developmental testing on my child.

I give permission for 2 surveys to be mailed to me to voluntarily complete when my child is at least 18 months of age.

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
_____	_____
Witness to Subject's Signature (Print Name)	Witness to Subject's Signature (Signature)
_____	_____
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

HIPAA AUTHORIZATION:

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

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.

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

Signature Page for Subjects 7 - 13 Years of Age

Printed Name of Subject: _____

I am the ( ) parent ( ) legal guardian of the subject named above. All of my questions have been answered to my satisfaction. I agree to the participation of the child named above in this research study.

Printed Name of Parent or Legal Guardian: _____

Signature: _____ Date:_____ Time: _____

Printed Name of Witness to Parent's Signature: _____

Signature: _____ Date:_____ Time: _____

I certify that I have explained this research study to the subject named above in language s/he could understand and that was appropriate to his/her age and ability to comprehend. The subject has verbally given his/her assent to participate in the research. I have also discussed the study described above with the subject's parent or legal guardian. Any questions have been answered to their satisfaction.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date:_____ Time: _____

Signature Page for Subjects 14-17 Years of Age

I have read this entire form. All of my questions have been answered to my satisfaction. I agree to participate in this research study.

Printed Name of Subject: _____

Signature: _____ Date:_____ Time: _____

I am the ( ) parent ( ) legal guardian of the subject named above. All of my questions have been answered to my satisfaction. I agree to the participation of the subject named above in this research study.

Printed Name of Parent or Legal Guardian: _____

Signature: _____ Date:_____ Time: _____

Printed Name of Witness to Parent's Signature: _____

Signature: _____ Date:_____ Time: _____

I certify that the study described above has been explained to the subject named above in language s/he could understand and that was appropriate to his/her age and ability to comprehend. The subject has freely given his/her assent to participate. I have also discussed the study described above with the subject's parent or legal guardian. Any questions have been answered to their satisfaction.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date:_____ Time: _____