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

TITLE OF STUDY : Adverse Childhood Effects, Resilience, and SUD: Maternal and Baby Outcomes in the First Year of Life

PRINCIPAL INVESTIGATOR : Dr. Alla Kushnir, MD

DEPARTMENT : Pediatrics

PHONE NUMBER(S) : 856-342-2265, 213-379-0010, 443-545-9320

SPONSOR : Cooper University Hospital Department of Pediatrics

What does informed consent for a research study involve?

You and your baby are being invited to take part in a research study. This form is part of an informed consent process. It will give you information to help you decide if you and your baby want to volunteer for this research study. Volunteering means you choose to have you and your baby take part in this study. You and your baby do not have to take part in this study to receive treatment at Cooper Hospital. The study doctor and her team will discuss how you and your baby will be involved in this research study. After, you and a member of the study team will sign this consent form. and you will be given a copy to keep. If you have questions at any time during the research study, you should feel free to call any of the team members listed above and ask your questions until you receive answers that satisfy you.

Who is paying for this research and where is it being done?

This study is being carried out only in Cooper University Hospital Department of Pediatrics. There is no funder for this study.

What is the purpose of this research study?

The purpose of this study is to understand if maternal and baby health outcomes can be identified early through Adverse Childhood Experience (ACE) questionnaire and the 7Cs Tool questionnaire. The ACE questionnaire includes 10 questions asking if you previously experienced any form of childhood trauma (example: physical, verbal, or sexual abuse).

The 7Cs Tool questionnaire reflects 7 disciplines such as character, confidence, and connection, for which three statements are provided and the participants can choose the answer that best describes them. We hope that this information will help doctors improve care for mothers who have a history of substance use and their babies.

Who may or may not take part in this study?

You and your baby are being asked to take part in this study because you are currently being treated for a history of substance use and are pregnant. To take part in this study:

- You must be at least 18 years old.
-You must be pregnant and have a history of substance use.

How long will the study take and how many people will take part?

You and your baby's will be included in this study for the duration of your pregnancy and 1 year after pregnancy. You and your baby's participation in this study will not be more than 2 years.

100 mothers (and children from their respective pregnancies) at Cooper Hospital will be in the study.

What will you be asked to do if you take part in this study?

You will be asked to sign this consent form to give your permission to allow the research study investigators to give you the 7Cs Tool questionnaire and Adverse Childhood Experiences (ACE) Questionnaire to answer. Your and your baby's information and answers will be kept confidential. You are giving us permission for us to follow up with you and your baby through phone calls or by looking at your and your baby's chart and record information about your medical history. We will collect this information at certain time points after your child is born (i.e. 2 month, 4 months, 6 months, 12 months, etc). The information we will collect are:

- Demographics (for example: age, gender, and race)
- Medical history

Our follow-up questions will include:

- The status of your baby's health
- The number of emergency room visits for your baby, if any
- Your baby's vaccination record
- Updates on your treatment for substance use

What are the risks and/or discomforts from participating in this study?

Health risks to you and your baby are not anticipated. You and your baby will have regular access to treatment and follow-up visits, which follow the normal standard of care at Cooper Hospital. Being involved in this study will result in loss of confidentiality of information that has been collected for research. In some cases, re-traumatization may occur and necessary resources will be made available to you.

Will you be given the results of your scores?

The results of this ACE + 7C questionnaire will be a cumulative score of childhood experiences. This score does not directly equate with any clinical findings at this time. Therefore, the results of the completed questionnaire will not be shared with you or your baby.

Are there any benefits if you take part in this study?

There is no direct benefit to subjects who participate in this study. However, the information learned from this study may benefit people in the future.

What are your alternatives (other choices) if you do not take part in this study?

The alternative is to not participate in this study.

When can your participation be terminated by the investigator?

If your baby passes away during pregnancy or at delivery, while you are enrolled in the study, your participation in the research will be terminated.

How will information about you and your baby be kept private?

Every step will be taken to make sure your and yours baby's information is kept private. A number will be used instead of your and your baby's name on all question forms. All of the information we collect will be kept in a locked cabinet in the investigating doctor's office. If the results of the study are presented publically, for example during a scientific meeting or in a publication, the doctors and study team will not use you or your name or any other information that can identify you or your baby.

Will there be any costs to you to take part in this study?

There is no cost to participate in this study

Will you be paid to take part in this study?

You and your baby will not receive any compensation for participating in this study.

What will happen if you become sick or hurt because you and your baby are in this study?

If you believe that you or your baby have been injured or become ill because of participation in this study, you should call the Chief Medical Officer or his representative at 856-342-3071.

What will happen if you and your baby do not wish to take part or decide not to stay in this study?

You and your baby do not have to be part of this study. If you decide to be in the study, you and your baby may quit at any time. Your decision not to participate or your choice to drop out of the study will not affect your and your baby's care at Cooper Hospital either now or in the future. Either way, the doctors at Cooper Health System will continue to treat you and your baby as intended. If you decide to quit the study, please contact the investigator at the phone number listed on the front of this consent form.

Will you be told about new information that might affect your decision to take part in this research?

During the study, you will be told if any new information is obtained that could affect your willingness to stay in the study. If new information about the questionnaires are obtained after you have finished the study and that information could affect you or your baby, the investigators will inform you.

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

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 and your baby, how this information will be used, and who will be able to see the information. You also have the right to see yours and your baby's 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 you and your baby's health information for this research study.

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

- There is an Institutional Review Board that oversees research in the Cooper Healthcare System. People who represent this Institutional Review Board may review your and your baby's health information because they need to see how the study is going.
- Other people who work for the Cooper Healthcare System or its affiliated health care providers may look at your and your baby's health information for the following reasons:
    - They need to fulfill orders (made by the investigators) for hospital and health care services (e.g., laboratory tests, diagnostic procedures) related to your and your baby's participation in the research study.
    - They need to address correct payment for tests and procedures ordered by the investigators.
    - They need to perform internal hospital operations (e.g. quality assurance).

You may already have a copy of Cooper Healthcare System'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 and your baby's 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. 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 the investigators listed on the front of this consent form.

You are authorizing us to use and disclose your PHI indefinitely. You may revoke this authorization to use and share your PHI at any time by contacting the principal investigator, in writing, at the address on the front of this form. If you decide not to authorize the investigator to use and disclose your PHI or you revoke this authorization, you will no longer be able to participate in this research study, and the use or sharing of future PHI will be stopped. However, the PHI that has already been collected may still be used.

Whom should you contact if you have questions?

If you have any questions about the research, you may contact the investigators listed on the front of this consent form. They are responsible for the conduct of the research at Cooper Hospital. They are affiliated with the Cooper Health System. Their address is 1 Cooper Plaza., Camden, NJ, 08103. They can be reached at the phone numbers given on the first page of this form.

You should call the Chief Medical Officer or his representative at (856-342-3071)

- if you have any questions about your rights as a research subject
- if you believe that you have not been told about all the risks, benefits, and alternative treatments

- if you believe that you are being forced to stay in this study when you do not want to
- if 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 or your baby's 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.

May you refuse to give your and your baby's authorization (permission) for the use of your and your health information for the purpose of this research study?

You do not have to give your and your baby's authorization to use and disclose 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 disclose your and your baby's health information, you and your baby may not be in the research study.

If you decide not to allow the investigators to use and disclose your and your baby's health information for this research study it will not affect your or your baby's care at Cooper Healthcare System, its affiliated health care providers, or hospitals now or in the future.

May you withdraw your and your baby's authorization (permission) for the use of your health information for this research study?

You may decide at any time that you no longer want the investigators to use and disclose your and your baby's health information. In that case, you and your baby will not be able to continue in this research study. The investigator and research staff will stop collecting health information from you and your baby for this study. In addition, research staff will stop using your and your baby's health information. They will also stop disclosing (releasing) your information to the parties described above, with certain exceptions. 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. You may also decide to give consent for the investigator to continue to collect your health information after you and your baby 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 One Cooper Plaza, Dorrance Suite 755,

Camden, NJ 08103. This decision will not affect your or your baby's care at Cooper Healthcare System, its affiliated health care providers, or hospitals now or in the future.

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

The investigators may continue to use and disclose your and your baby's 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 and your baby's information for this study at any time in the future

VOLUNTARY PARTICIPATION

I voluntarily consent to take part in this study. I also agree to the use and disclosure of my protected health information for this study. The study staff have discussed this research study with me. I have had adequate time to read this form and to ask questions about it. I understand that if I refuse to participate in this study, decide to stop participating, or choose to stop letting my PHI be used, it will not affect my treatment at Cooper University Hospital.

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

I understand by signing this form I am not giving up any of my legal rights. I will be given a copy of this consent form for my records.

Printed Name of Participant (mother) : _____

Printed Name of participant(s) (children) : _____

Signature of mother: _____ Date: _____ Time:

Printed Name of Witness to Subject's Signature: _____

Signature: _____ Date: _____ Time:_____

I have discussed the study described above with the subject.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date: _____ Time: