INFORMATION PAPER FOR PARTICIPATION IN A CLINICAL TRIAL AND CONSENT FORM FOR CAPABLE SUBJECTS

Obstetrics and Obstetric Pathology Unit

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PREECLAMPSIA AND FETAL HEART MALFORMATIONS: LOOKING TO MATERNAL HEART (MaMaH)

Fondazione Policlinico Universitario A. Gemelli IRCCS

Obstetrics and Obstetric Pathology Unit

Principal investigator: Silvia Salvi

Dear Madam,

The information contained in the following paper is very detailed. We would like to ask that you make the decision to accept or decline participation only after reading this sheet and having had a thorough discussion with a member of the trial team. This person should take the time necessary to fully understand the proposal.

You have the right to be informed about the purpose and characteristics of the trial so that you can freely and consciously decide whether to participate.

This document is intended to inform you about the nature of the trial, its purpose, and what it will mean for you and your child.

Please read the following carefully. The researchers involved in this project are available to answer your questions. No question you may have is trivial: don't be afraid to ask!

In addition to us, you can discuss the proposal contained in this document with your family doctor, your family members and other trusted people. Please take all the time you need to decide. You may take an unsigned copy of this document home to think about or discuss with others before making a decision. If you decide not to participate in the trial, you will still receive the best possible care.

Your refusal will in no way be interpreted as a lack of trust.

The Principal Investigator

INFORMATION SHEET

Dear Madam,

A medical-scientific research entitled "**Preeclampsia and Fetal Cardiac Malformations: Looking to Maternal Heart**" **(MaMaH)** is ongoing at Fondazione Policlinico Universitario Agostino Gemelli-IRCCS.

This is a national, single-center study.

To conduct this research, we would like to avail ourselves of the collaboration and availability of people who, like you, meet the scientific requirements for the evaluation that will be performed. Whether or not you decide to participate in this study will have no impact on the care you receive, and the doctors will continue to monitor you with due care.

However, before you decide to accept or decline to participate, we ask you to read these pages carefully, taking all the time you need, and to ask for clarification if you have not fully understood or require further clarification. Furthermore, if you wish, you can seek the opinion of your family members or a trusted physician before making your decision.

WHAT THE STUDY AIMS

The overall objective of the study is to identify, through the use of a new procedure (the USCOM-1A device), hemodynamic (i.e., cardiovascular) characteristics of women whose babies have a congenital heart anomaly, or congenital heart disease, both during pregnancy and immediately after delivery.

Furthermore, with the research presented here, we intend to correlate these data with the prevalence of preeclampsia in the population of pregnant women with fetuses affected by congenital heart disease.

In this way, we hope to gain a better understanding of fetal pathology and thus improve current clinical practice in maternal-neonatal management.

This study is expected to last three years (3 years) and will involve 108 women who, like you, have a baby with a congenital heart anomaly, or congenital heart disease.

WHAT YOUR PARTICIPATION IN THE STUDY INVOLVES

If you decide to participate in the study, you will undergo an assessment of your cardiac function parameters using non-invasive hemodynamic monitoring (USCOM-1A).

This test lasts approximately 2 minutes and involves placing a small ultrasound transducer (the same principle as the ultrasound scans used to monitor your baby's well-being and therefore harmless to both you and your baby's health) at the level of your sternal notch (at the base of your neck) to record approximately 30 seconds of the cardiac cycle, after measuring your blood pressure.

This monitoring system indirectly measures the velocity of blood flow through the aortic valve with each heartbeat and, based on this value, provides parameters indicating maternal cardiac function (cardiac output, stroke volume, mean arterial pressure, peripheral vascular resistance).

This assessment will be performed upon diagnosis of congenital heart disease and then every two weeks until delivery. A further assessment will be performed immediately postpartum (within 72 hours).

Finally, data relating to the pregnancy and the outcome of the pregnancy in terms of both mother and baby's health will be collected.

Participation in the trial will not entail any additional costs for you nor will you receive any compensation.

WHAT ARE THE RISKS OF PARTICIPATION IN THE STUDY

Participation in the study will not pose any risk to the patient, as it does not involve invasive tests or therapeutic treatments.

WHAT ARE THE BENEFITS YOU MAY RECEIVE BY PARTICIPATING IN THE STUDY

There are no expected direct benefits for you from participating in this study, but your participation will allow us to acquire additional information about the condition your child is suffering from.

STUDY RESULTS AND CONFIDENTIALITY OF THE INFORMATION COLLECTED

All data collected during your participation in the study will be pseudonymized, meaning you will be assigned a code that cannot be directly linked to you and will be stored electronically. This code will not allow you or your child to be identified outside the medical treatment center.

Regarding the personal data processing, you have to refer to the specific information for the expression of consent to the processing of personal data that will be given to you simultaneously, on a separate sheet.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY

You are free not to participate in the study. In this case, you will still receive all standard treatments for your condition, without any penalty, and your doctors will continue to monitor you with the necessary care.

INTERRUPTION OF THE STUDY

Your participation in this research program is completely voluntary, and you may withdraw from the study at any time by notifying the Investigator. In this case, the data collected up to the time of withdrawal will not be considered in the aggregated and anonymous results for the final analysis.

INFORMATION ABOUT STUDY RESULTS

Upon your request, at the end of the study, the study results in general and those concerning you in particular may be communicated to you.

WHO ORGANIZES AND PROMOTES THIS STUDY?

The study is promoted by Fondazione Policlinico Universitario A. Gemelli IRCCS.

We thank you for your attention and the time you have dedicated to reading and discussing this document. If you decide to participate, you will be provided with a copy of this Information paper and a signed consent form to store.

FURTHER INFORMATION

The following people will be available for further information and communications during the study:

- Silvia Salvi; silvia.salvi@policlinicogemelli.it; cell. 339/7172786

- Roberta Rullo; rulliroberta90@gmail.com; cell. 349/8918971

- Federica Totaro Aprile; federica.totaroaprile01@icatt.it; cell. 334/7347894

The study protocol proposed to you has been drafted in accordance with the current revisions of the European Union's Good Clinical Practice Guidelines and the World Medical Association's Declaration of Helsinki for clinical trials involving human subjects, and has been approved by the Ethics Committee of this facility. You may report any matters you deem appropriate regarding the trial involving you to the Ethics Committee of this facility.

CONSENT STATEMENT

(For the Child's Mother)

I, _____

I DECLARE

☐ that I have received from Dr. _____ comprehensive explanations regarding my request to participate in the research in question, as reported in the information section, a copy of which was previously provided to me as part of this consent form on _____.

☐ that the nature, purposes, procedures, expected benefits, risks, and potential drawbacks have been clearly explained to me and that I understand them;

☐ that I have had the opportunity to ask the study investigator any questions I may have and have received satisfactory answers;

☐ that I have had sufficient time to reflect on the information received;

☐ that I have had sufficient time to discuss the information with third parties;

☐ that I am aware that the research may be interrupted at any time;

☐ that I have been informed that the results of the study will be made known to the scientific community, protecting my identity in accordance with current privacy legislation;

☐ that I understand that any choice expressed in this consent form may be revoked at any time and without justification;

☐ that I have received a copy of this consent form.

_____

Date

_____

Signature of the Child's Mother

_____

Date

_____

Signature of the doctor who informed the patient

(if the woman cannot read and/or write)

In this case:

I, …….. testify that Dr. …… has thoroughly explained to Ms. …….

the characteristics of the experimental study in question, as reported in the attached information paper and that she, having had the opportunity to ask all the questions she deemed necessary, freely agreed to participate in the study.

Date …….

Signature of independent witness ……..

Date ……..

Signature of the doctor who provided the information to the patient ……

DECLARATION OF THE DOCTOR WHO COLLECTED THE CONSENT

I, _____ (NAME-SURNAME)

in my capacity as

☐ Principal Investigator

☐ Principal Investigator's Delegate

DECLARES

that the Patient has voluntarily consented to participate in the trial.

I also declare that:

☐ I have provided the Patient with comprehensive explanations regarding the purposes of the trial, the procedures, the possible risks and benefits, and the possible alternatives;

☐ I have verified that the Patient has sufficiently understood the information provided;

☐ I have given the Patient the necessary time and opportunity to ask questions regarding the Trial;

☐ I have clearly explained the possibility of withdrawing from the trial at any time or changing the choices made;

☐ I have not exercised any coercion or undue influence in obtaining this consent;

☐ Provide the patient with information on how the trial results will be communicated to him or her.

Place and date

First name and last name of the physician who provided the information and obtained the consent

Signature (and stamp)

CONSENT STATEMENT FOR NEWBORN DATA COLLECTION

(For child's parents)

I, (Mother): _____

I, (Father): _____

declare that I have received from Doctor _____

exhaustive explanations regarding the purposes and methods of data collection from my child, as reported in the attached information sheet, a copy of which was previously provided to me.

I further declare that I have been able to discuss these explanations, that I have asked all the questions I deemed necessary and have received satisfactory answers, and that I have had the opportunity to inquire about the details of the study from people I trust.

I therefore freely consent to the collection of my child's data for the purposes and according to the methods of the study in question.

_____

Date

_____ _____

Signature of the Child's Mother Signature of the Child's Father

_____

Date

_____

Signature of the doctor who informed the patient

(if one of the parents is unable to read and/or write)

In this case:

I, …….. testify that Dr. …… has thoroughly explained to Mr. …….. the characteristics of the study in question, as reported in the attached information paper, and that he/she, having had the opportunity to ask all the questions he deemed necessary, has freely agreed to give his consent for the collection of his child's data.

Date…….. Signature of independent witness ……..

Date……. Signature of the doctor who provided the information to the patient ……