INFORMATION SHEET FOR PARTICIPATION IN A CLINICAL STUDY AND INFORMED CONSENT FORM FOR PARENTS / GUARDIANS / LEGAL REPRESENTATIVES

v.1.0 dated 16/02/2026

TITLE: Doppler assessment of the ophthalmic artery after 37 weeks of gestation and adverse intrapartum fetal outcomes (OPHELIA study)

INSTITUTION: Fondazione Policlinico Universitario "A. Gemelli" IRCCS

DEPARTMENT/OUTPATIENT CLINIC/SERVICE: Obstetrics and Obstetric Pathology Unit

INVESTIGATOR: Prof. Tullio Ghi

TELEPHONE: +39 3385070025

Dear Madam/Sir,

The information contained in the following information sheet is very detailed. We ask you to decide whether to accept or refuse participation of your child/the person under your guardianship/the person you legally represent ONLY after reading this sheet and having had a THOROUGH DISCUSSION with a member of the study team, who must devote the TIME NECESSARY for you to fully understand what is being proposed.

It is your right to be informed about the purpose and characteristics of the study so that you can make an informed and free decision as to whether your child/the person under your guardianship/the person you legally represent should participate.

This document is intended to inform you about the nature of the study, its purpose, and what participation will involve for your child/the person under your guardianship/the person you legally represent, including his/her rights and responsibilities.

Please read the information below carefully. The researchers involved in this project, indicated at the beginning of this document, are available to answer your questions. No question that comes to mind is trivial: please do not hesitate to ask it.

In addition to discussing this proposal with us, you may discuss the contents of this document with your general practitioner, your family members, and other people you trust. Take all the time you need to decide. You may take home an unsigned copy of this document to consider it or discuss it with others before making a decision. If you decide not to allow your child/the person under your guardianship/the person you legally represent to participate in the study, he/she 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 Parent/Guardian/Legal Representative,

At Fondazione Policlinico Universitario Agostino Gemelli IRCCS, a study entitled "Doppler assessment of the ophthalmic artery after 37 weeks of gestation and adverse intrapartum fetal outcomes (OPHELIA study)" is planned.

This is a national, single-center research study designed to investigate a new ultrasound diagnostic procedure in order to identify which babies may be at greater risk of stress during labor.

To conduct this research, we would like to ask for the cooperation and availability of people who, like your child/the person under your guardianship/the person you legally represent, meet the scientific eligibility requirements for the assessment to be performed. Your decision whether or not to participate in this study will have no impact on the care that your child/the person under your guardianship/the person you legally represent receives, and the doctors will continue to provide him/her with appropriate care.

Before you decide whether to accept or refuse participation, however, we ask you to read these pages carefully, taking all the time you need, and to ask for clarification if anything is unclear or if you need further information. In addition, if you wish, before deciding you may seek the opinion of your family members or a doctor you trust.

WHAT IS THE PURPOSE OF THE STUDY?

The general objectives of the study are:
1. To investigate a new ultrasound parameter in order to identify which fetuses may be at greater risk of stress during labor;
2. To improve clinical practice within the context of increasingly personalized medicine.

WHAT DOES THE STUDY INVOLVE?

The study design is as follows: once you are admitted to our Obstetric Pathology Unit for elective induction of labor, an ultrasound examination will be performed on your eyelid. More specifically, the ophthalmic artery of your eye will be sampled and the diameter of your optic nerve will be measured. After the birth of your child, measurement of the diameter of your optic nerve will be proposed again.

WHAT DOES PARTICIPATION OF YOUR CHILD/THE PERSON UNDER YOUR GUARDIANSHIP/THE PERSON YOU LEGALLY REPRESENT IN THE STUDY INVOLVE?

If you agree to allow your child/the person under your guardianship/the person you legally represent to participate in this study, he/she will undergo a medical-history assessment to determine whether all study inclusion criteria are met. Clinical data relating to delivery and the neonatal period will subsequently be collected: birth weight, Apgar score, umbilical cord pH, and any admission to the Neonatal Intensive Care Unit (NICU).

Your child will have no direct involvement in the study. Clinical data concerning the birth will simply be collected, as specified in the previous paragraph.

The study will last 24 months, while the expected recruitment period is 18 months. A total of 1,477 newborns, born to mothers who previously underwent induction of labor, will participate in this research.

Participation in the study will not entail any additional costs for your child/the person under your guardianship/the person you legally represent, nor will any compensation be provided.

WHAT ARE THE RISKS ASSOCIATED WITH PARTICIPATION IN THE STUDY?

Participation in the study will not involve any risk for your child, as only clinical data will be collected.

WHAT BENEFITS MAY YOUR CHILD/THE PERSON UNDER YOUR GUARDIANSHIP/THE PERSON YOU LEGALLY REPRESENT RECEIVE FROM PARTICIPATING IN THE STUDY?

The following benefits may be expected from participation in this study: there will be no direct benefit to your child/the person under your guardianship/the person you legally represent, but participation may contribute to scientific progress and benefit other newborns in the future.

STUDY RESULTS AND CONFIDENTIALITY OF THE INFORMATION COLLECTED

All data concerning your child will be pseudonymized, meaning that he/she will be assigned a code that cannot be directly linked to his/her identity, and the data will be recorded electronically. This code will not allow your child/the person under your guardianship/the person you legally represent to be identified outside the medical center where the data are processed.

With regard to the processing of personal data, please refer to the specific information sheet for consent to personal data processing, which will be provided to you at the same time on a separate sheet.

WHAT HAPPENS IF YOU DECIDE NOT TO ALLOW PARTICIPATION IN THE STUDY - POSSIBLE ALTERNATIVE TREATMENTS

You are free not to allow your child/the person under your guardianship/the person you legally represent to participate in the study. In this case, he/she will continue to receive all standard therapies and care provided after birth, without any penalty, and the doctors will continue to provide appropriate care.

WHAT HAPPENS IN THE EVENT OF HARM?

This study is covered by the institution's insurance policy.

DISCONTINUATION OF THE STUDY

Your participation in this research program is entirely voluntary and you may withdraw your child/the person under your guardianship/the person you legally represent from the study at any time by informing the Investigator. In this case, the data collected up to the time of withdrawal will not be considered in aggregated and anonymous form in the final analysis.

Likewise, the study may be discontinued if:
1. the physician does not observe a benefit, or if undesirable effects or other circumstances occur;
2. new information becomes available and the study is no longer in the best interest of your child/the person under your guardianship/the person you legally represent;
3. the agreed rules for participation in the study are not followed;
4. the study is discontinued by the competent authorities or by the sponsor.

In any event, you must continue to entrust your child/the person under your guardianship/the person you legally represent to the medical and midwifery staff for appropriate neonatal monitoring.

If data become available that could influence the decision to continue the study, you will be promptly informed. If you decide to continue the study, you may be asked to sign a new informed consent form highlighting the update.

INFORMATION ABOUT THE STUDY RESULTS

If you request it, at the end of the study you may be informed of the study results in general and, in particular, of those concerning your child/the person under your guardianship/the person you legally represent.

FURTHER INFORMATION

For further information and communications during the study, you may contact the following staff:
1. Prof. Tullio Ghi: +39 3385070025
2. Dr. Alessandro Petrecca: +39 3479212418

We point out the importance of informing your general practitioner in order to avoid interactions with medications/treatments; your doctor may contact the center for any information.

The study protocol proposed to you has been reviewed and approved by CET Lazio Area 3. Among other things, the CET verified the study's compliance with Good Clinical Practice and with the ethical principles expressed in the Declaration of Helsinki, and that your safety, rights, and well-being are protected.

If you consider it appropriate to report events or facts relating to the study in which you are participating to persons not directly involved in the study itself, you may contact the CET that approved the study (Comitato Etico Territoriale Lazio Area 3).

WHO ORGANIZES AND SPONSORS THIS STUDY?

The study is sponsored by Fondazione Policlinico Universitario Agostino Gemelli IRCCS.

Thank you for the attention and time you have devoted to reading and discussing this document.

If you decide to allow your child/the person under your guardianship/the person you legally represent to participate in the Study, you will be provided with a copy of this Information Sheet and a signed consent form to keep.

CONSENT STATEMENT

(This statement must be personally signed and dated by the Parents or guardian/legal representative and by the physician who conducted the informed consent discussion.)

I, the undersigned: _____(father)
I, the undersigned: _____(mother)

I, the undersigned: _____(legal representative/guardian)
of _____

DECLARE

■ that I have received from Dr. _____ comprehensive explanations regarding the request to participate in the research study in question, as described in the information section, a copy of which had previously been provided to me and which forms part of this consent, and of which I received a copy on _____;

■ that the nature, purposes, procedures, expected benefits, possible risks and inconveniences, and alternative treatment options to the proposed clinical study have been clearly explained to me and that I have understood them;

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

■ that I have had sufficient time to consider the information received;

■ that I have had sufficient time to discuss it with third parties;

■ that I have been informed that the study protocol and all forms used received a favorable opinion from the competent CET;

■ that I am aware that the research may be discontinued at any time;

■ that I have been informed that I will be made aware of any new information that could affect the safety of the research and that, for any problem or further questions, I may contact the principal investigator or his/her collaborators;

■ that, for the best protection of the health of my child/the person under my guardianship/the person I legally represent, I am aware of the importance of informing the pediatrician/general practitioner about the study in which I agree to allow my child/the person under my guardianship/the person I legally represent to participate;

■ I am aware of the importance of providing the investigator with all information concerning my child/the person under my guardianship/the person I legally represent (medications, side effects, etc.);

■ that I have been informed that the study results will be made known to the scientific community while protecting the identity of my child/the person under my guardianship/the person I legally represent in accordance with current privacy legislation;

■ that I am aware that any choice expressed in this consent form may be revoked at any time and without any justification;

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

Place and date _____

Mother's first and last name (block letters) _____
Mother's signature _____

Father's first and last name (block letters) _____
Father's signature _____

Guardian/legal representative's first and last name (block letters) _____

Guardian/legal representative's signature _____

STATEMENT OF THE PHYSICIAN WHO OBTAINED CONSENT

I, the undersigned (FIRST NAME-LAST NAME) _____

in my capacity as
■ Principal Investigator
■ Delegate of the Principal Investigator

DECLARE

That Mr./Ms. (insert name) _____, in his/her capacity as parent/guardian/legal representative, voluntarily consented to participation in the study.

I further declare that I:

■ provided the parent/guardian/legal representative with comprehensive explanations regarding the purposes of the study, the procedures, possible risks and benefits, and possible alternatives;

■ verified that the parent/guardian/legal representative sufficiently understood the information provided;

■ allowed the parent/guardian/legal representative the necessary time and opportunity to ask questions regarding the study;

■ clearly explained the possibility of withdrawing the minor/person represented/person under guardianship from the study at any time or changing the choices made;

■ did not exercise any coercion or undue influence in requesting this consent;

■ provided the parent/guardian/legal representative with information on how the study results will be communicated to him/her.

_____

Place and date _____

_____
First and last name (block letters) of the physician who provided the information and obtained consent

Signature (and stamp) _____

This form is an integral part of the informed consent documentation and must be kept together with the informed consent information sheet.