INFORMATION SHEET FOR PARTICIPATION IN A CLINICAL STUDY AND INFORMED CONSENT FORM

for an adult patient capable of personally providing informed consent

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,

The information contained in the following information sheet is very detailed. We ask you to agree to participate in the study ONLY after carefully 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 to participate.

This document is intended to inform you about the nature of the study, its purpose, and what participation will involve for you, including your 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 participate in the study, you will still receive the best possible care for patients with your condition.

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

The Principal Investigator

INFORMATION SHEET

Dear Madam,

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 you, 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 you receive, and the doctors will continue to provide you 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 YOUR PARTICIPATION IN THE STUDY INVOLVE?

If you agree to participate in this study, you will undergo an interview to verify that your condition meets the requirements for participation. During this interview, a detailed medical and obstetric history will be collected. Once it has been established that you meet all the inclusion criteria for the study, you will be offered a targeted fetal ultrasound examination to assess fetal well-being indices as part of normal clinical practice (e.g., assessment of the umbilical artery and fetal middle cerebral artery). In addition, as an experimental procedure, assessment of the ophthalmic artery and optic nerve diameter will be proposed; the latter will subsequently be repeated after the birth of your child.

Clinical data relating to induction, labor, and delivery will be collected: age, weight, parity, induction method used, gestational age at delivery, mode of delivery (e.g., spontaneous vaginal delivery, operative vaginal delivery, cesarean delivery), estimated blood loss after delivery, use of oxytocin during labor, epidural analgesia, and any episiotomy.

The study will last 24 months, while the expected recruitment period is 18 months. A total of 1,477 patients who, like you, will undergo induction of labor will participate in this research.

Participation in the study will not entail any additional costs for you, nor will any compensation be provided.

WHAT ARE THE RISKS ASSOCIATED WITH PARTICIPATION IN THE STUDY?

Participation in the study may involve some risks related to the planned assessments. In particular, you may experience itching of the eyelid following application of the sterile gel used with the ultrasound probe.

WHAT BENEFITS MAY YOU RECEIVE FROM PARTICIPATING IN THE STUDY?

The following benefits may be expected from participation in this study: there will be no direct benefit to you, but participation may contribute to scientific progress and benefit other patients in the future.

STUDY RESULTS AND CONFIDENTIALITY OF THE INFORMATION COLLECTED

All your data will be pseudonymized, meaning that you will be assigned a code that cannot be directly linked to you, and the data will be recorded electronically. This code will not allow you 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 PARTICIPATE IN THE STUDY - POSSIBLE ALTERNATIVE TREATMENTS

You are free not to participate in the study. In this case, you will continue to receive all standard therapies and care appropriate to your condition, without any penalty, and the doctors will continue to provide you with 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 from the study at any time by informing the Investigator, Dr. Alessandro Petrecca or Prof. Tullio Ghi. 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 your best interest;
3. you do not follow the agreed rules for participation in the study;
5. the study is discontinued by the competent authorities or by the sponsor.

In any event, you must continue to rely on the medical and midwifery staff for the management of your labor and delivery.

If data become available that could influence the decision to continue the study, you will be promptly informed. If you decide to continue in 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 you.

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

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 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 patient and by the physician who conducted the informed consent discussion.)

I 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 my health, I am aware of the importance of informing my general practitioner about the study in which I agree to participate;

■ that I am aware of the importance of providing the investigator with all information concerning me (medications, side effects, etc.);

■ that I have been informed that the study results will be made known to the scientific community while protecting my identity 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 _____

_____
Patient's first and last name (block letters)

Patient's signature _____

(If the patient is unable to read or sign, a witness independent of the investigator and sponsor must be present throughout the informed consent discussion. The witness must personally sign and date the informed consent statement after the form itself and any other written information have been read and explained to the subject and the subject has given verbal consent to participate in the study.)

In this case:

I, the undersigned ....., hereby witness that Dr.....has fully explained to Mr./Ms. ..... the characteristics of the experimental study in question, as described in the attached information sheet, and that, having had the opportunity to ask all questions considered necessary, the patient freely agreed to participate in the study.

Date ..... Signature of the independent witness .....

Date ..... Signature of the physician who provided the information to the patient .....

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 the Patient voluntarily consented to participate in the study.

I further declare that I:

■ provided the Patient with comprehensive explanations regarding the purposes of the study, the procedures, possible risks and benefits, and possible alternatives;
■ verified that the Patient sufficiently understood the information provided;
■ allowed the Patient the necessary time and opportunity to ask questions regarding the Study;
■ clearly explained the possibility of withdrawing 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 patient 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.