

Participant Information Sheet: Predicting Placental Dysfunction

Dear prospective participant,

You are invited to take part in a study about placental dysfunction, which means the placenta is not developing normally and working as well as expected during pregnancy. When this happens, the placenta does not fully meet the needs of the baby. This can result in the mother developing pre-eclampsia and the baby failing to grow normally. In the most severe cases, the condition can become life-threatening for the mother and/or the baby.

Even with close monitoring of the mother and unborn baby during pregnancy, the diagnosis of placental dysfunction currently cannot be confirmed until after childbirth, when its complications have already occurred. The key to preventing these complications is the ability to diagnose placental dysfunction during pregnancy. For this reason, we wish to identify substances in maternal blood that are associated with the condition. In this way, we hope to diagnose placental dysfunction during pregnancy and subsequently provide appropriate monitoring and treatment.

The study has received ethical approval from the National Bioethics Committee (Vísindasiðanefnd), reference VSN2603004.

The Principal Investigator (ábyrgðarmaður) is Dr. Jóhanna Gunnarsdóttir, Head of the Academic Department of Obstetrics and Gynaecology, Landspítali University Hospital and University of Iceland, johagunn@landspitali.is.

Participation in the study consists of:

- A blood sample at 12 weeks of pregnancy, collected at the same time as the routine blood sample taken as part of your pregnancy care. A second blood sample at 36 weeks of pregnancy. Blood samples will be stored in the Landspítali biobank for the measurement of various substances, including proteins derived from the placenta. These analyses will be carried out at Landspítali University Hospital and by collaborating organisations.
- Participants will be asked to answer questions about their health, physical activity, and use of Hjartamagnýl (low-dose aspirin).
- The placenta will be examined after childbirth. Microscopic images of placental tissue will be stored, and samples from the placenta will be preserved in the biobank of the Department of Pathology at Landspítali for future analyses.
- Information relevant to the study about participants' health and birth outcomes will be obtained from medical records and other health information databases (such as databases maintained by the Icelandic Directorate of Health) and linked with measurements of substances in blood and/or the placenta to develop predictive models for placental dysfunction.



You are under no obligation to participate in this study. If you choose to participate, you are not required to answer all the questions, and you may decide separately whether genetic material may be isolated from your biological samples.

If you would like more information to help you decide whether to participate, you can receive it when you attend your 12-week ultrasound examination.

You may withdraw from the study at any time without this affecting the healthcare you or your child receive. If you decide to withdraw, your information will be deleted, and your biological samples will be destroyed. However, if the study results have already been published in a scientific publication, it will not be possible to remove the data on which those results were based. In that case, the data will no longer be identifiable as yours.

The risks associated with participation are negligible; however, blood sampling may cause bruising at the puncture site. Participants will not receive payment for taking part in the study. Although the findings of this research will benefit future generations, it is unlikely that participants themselves will benefit during subsequent pregnancies, as data collection and analysis will take several years.

If you choose to participate in the study, you will be asked to provide written informed consent confirming that you understand the purpose of the study. Before signing the Statement of Informed Consent, please read the information below carefully regarding data protection and the storage of biological samples. If you also choose to participate in the genetic component of the study, you will be asked to provide separate written informed consent for that part of the research. Genetic analysis of placental tissue would only be carried out if we contact you again after the birth of your child, and would in that case require the consent of both parents.

Further Information on Study Procedures and Data Protection

All information about you will be treated as confidential. The results of the study will be published without any personal identifiers and will always be presented as grouped data rather than results relating to individual participants. During data collection, personally identifiable information will be processed to verify the accuracy of the recorded information and to enable linkage with other health databases. Personal identifiers will be transferred securely to institutions such as the Icelandic Directorate of Health. Once data collection has been completed, only coded (pseudonymised) biological samples and health information will be used for research purposes. The pseudonymisation key linking the code to your Icelandic personal identification number (kennitala) will be stored securely within Landspítali and will be accessible only to the Principal Investigator and their designated deputy. Blood and placental samples will be stored in the biobanks at Landspítali and labelled only with the pseudonymisation code, not with your personal identification number. Health information and biomarker measurements will be combined in a research database that will be stored indefinitely in the Landspítali health information repository to support future research into factors that may predict placental dysfunction and help develop new treatment strategies. Any



future studies using these data or biological samples will always require approval from the National Bioethics Committee to ensure that they comply with scientific and ethical standards.

This study will be conducted in accordance with the Icelandic Act on Scientific Research in the Health Sector No. 44/2014 and the Icelandic Act on Data Protection and the Processing of Personal Data No. 90/2018. You have the right to request further information about how your personal data will be protected and about your rights as a participant in this research study.

General information about participation in scientific research can be found on the [website of the National Bioethics Committee](#).

Further information about this study is available from the Principal Investigator and on [the study website](#).

On behalf of the research team,

Dr. Jóhanna Gunnarsdóttir, Principal Investigator, Obstetrician and Associate Professor