Etude HOPE – Version 3.0 du 26/11/2018

PATIENT CONSENT FORM

Details about this study are provided in the specific newsletter provided to you.
Read this manual carefully and ask all the questions that you think will be useful.
If you agree to participate in this study, please complete the form below.

Title of the study : Assessment of uteroplacental vascularisation in early first-trimester pregnancy with contrast-enhanced ultrasound and 3D power Doppler angiography: protocol for a multicentre prospective study (HOPE).

SPONSOR : Centre Hospitalier Régional (CHR) de Metz-Thionville
CHR-METZ-THIONVILLE
Hôpital de Mercy 1, Allée du Château - CS 45001
57085 Metz Cedex 03.

I, the undersigned, Mrs. .... (full name in capital letters), declares to have understood the purpose and the modalities of this study, which were fully explained to me by the Doctor .... (full name in capital letters), investigator doctor. I received the specific information form that I had the opportunity to study carefully.
Answers have been made to all my questions.
I had a minimum of one hour to think about it before making my decision.

I freely agree to participate in this study under the conditions specified in this document: ☐ **Yes** ☐ **No**

My agreement was also requested for a placental sample for biological analysis.
I give freely my permission for the analysis of the placenta:
☐ **Yes** ☐ **No**

I accept that any new information becoming available during the study and that may have implications for me will be provided by the investigating doctor:
☐ **Yes** ☐ **No**

- ✓ I understand that my data and samples will not be used for any other purpose than this research.
- ✓ I agree to participate in this research under the conditions specified in the attached information form.
- ✓ I remain free to return to my decision at any time and not to participate in the study. I will then inform the investigator.
- ✓ No longer participating in this research will not affect my relationship with my doctors and will not call into question the quality of future care.
- ✓ I have been informed that in accordance with the regulation on clinical studies, the Committee for the Protection of Persons East III has given a favorable opinion for the realization of this study dated 05 / April / 2016 and the ANSM has given its authorization for the realization of this study dated 21 / June / 2016

- ✓ I have also been informed that in accordance with the law in force, an insurance contract has been taken out by the research sponsor.

All data concerning me, including my medical file, will remain confidential. I authorize their consultation only by the persons who collaborate in the research, the persons charged by the sponsor to control the quality of the study as well as by a representative of the health authorities.

- ➢ I agree that the data recorded during this research may be the subject of a computerized treatment by the promoter or on his behalf.

I was informed of the purpose of the data processing (I was told what the data would be used for) and the recipients of this data. I have noted that my rights of access, rectification, deletion, limitation and opposition provided by the General Data Protection Regulation (GDPR) are exercised at any time by the Investigator who follow me as part of the research and who knows my identity. I confirm being affiliated to a social security scheme.

- ➢ I give my consent to participate in this research.
- ➢ I may at any time request any additional information from the investigator.
- ➢ My consent does not relieve the investigator and sponsor of all of their responsibilities and I retain all my rights guaranteed by law.
- ➢ I understand that I have the right to be informed of the overall results of this research at the end of this research. They can be communicated to me by mail (or during a follow-up consultation) if I wish.

<table>
<tr><td colspan="2">TO BE COMPLETED BY THE PATIENT</td></tr>
<tr><td colspan="2">Date : …….
Signature of the patient</td></tr>
<tr><td colspan="2">TO BE COMPLETED BY THE INVESTIGATOR DOCTOR</td></tr>
<tr><td colspan="2">I, the undersigned Doctor ..... (full name in capital letters) confirms that she has fully explained to the patient the purpose and modalities of this study as well as its potential risks. I undertake to enforce the terms of this consent form, reconciling respect for individual rights and freedoms with the requirements of scientific work.
Phone number of the investigator: ……..</td></tr>
<tr><td>Signature of the investigateur :</td><td>Date : ……..</td></tr>
</table>

Done in two copies, one of which will be kept by the investigator and the other given to the patient.

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PATIENT CONSENT FORM

HOPE - complementary genetic study from placental samples

The details concerning this interventional research were communicated to you by the investigator verbally and were given to you in writing in a specific information document.

After reading this document and after asking the investigator all useful questions, if you agree to participate in this research, please complete the consent form below.

Title of the study : Assessment of uteroplacental vascularisation in early first-trimester pregnancy with contrast-enhanced ultrasound and 3D power Doppler angiography: protocol for a multicentre prospective study (HOPE).

SPONSOR : Centre Hospitalier Régional (CHR) de Metz-Thionville

CHR-METZ-THIONVILLE

Hôpital de Mercy 1, Allée du Château - CS 45001

57085 Metz Cedex 03.

By signing this consent form, I confirm the following:

• I understood the purpose and the modalities of this research, which were fully explained to me.

• I received the information document specific to this research and I had the opportunity to study each page carefully.

• I had a reflexion period before making my decision.

• I am compulsorily affiliated to a social security scheme.

• I declare that I am not placed under a system of legal protection of the adults (safeguard of justice, curatorship or trusteeship) and currently aimed by a proceeding tending for this purpose.

I was clearly informed:

- That I am free to accept or refuse to participate, and I am free to stop my participation in the course of research at any time. This will not influence the quality of care that will be provided to me.

- The purpose of the treatment (I was told what the data would be used for) and the recipients of this data. I have noted that my right of access, rectification and opposition provided by the law of 6 January 1978 relating to computers, files and freedoms is exercised at any time by the investigator who follows in the course of research and who knows my identity
- All data concerning me, including my medical file, will remain confidential and may be consulted by authorized persons (detailed in the attached information document) subject to professional secrecy.
- Placental data and samples may be transmitted to other national or international teams (outside the European Union) in the context of research collaborations, in a form that will not allow my direct or indirect identification.
- The placental samples can be preserved and reused in the same theme.
- An analysis of my genetic characteristics may be performed from my biological samples (as part of this research and / or for future research). This is not meant to identify or re-identify me based on my genetic characteristics.
- That I will be notified by the investigator in case of "diagnosis of a serious genetic abnormality" found during a genetic analysis: ☐ **Oui** ☐ **Non**

After having discussed and having obtained the answer to all my questions, I accept freely and voluntarily, under the conditions specified in the attached information document, to participate in the research that is proposed to me.

My consent does not relieve the investigator and sponsor of all of their responsibilities and I retain all my rights guaranteed by law.

I understand that I have the right to be informed of the overall results of this research at the end of this research. They can be communicated to me by mail (or during a follow-up consultation) if I wish.

Done in two copies, one of which will be given to me, the 2nd will be kept by the investigator.

TO BE COMPLETED BY THE PATIENT
Date: ___ / ___ / ___ Last name ……..First Name :…….. Signature of the person suitable for research:

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TO BE COMPLETED BY THE INVESTIGATOR DOCTOR
Date: ___ / ___ / ___ Last name ……First Name :…… I certify that the information requirements of the person who is willing to search for and obtain his free and informed consent have been met in accordance with the regulations in force. Signature of the Investigator:

Bertholdt C, *et al. BMJ Open* 2019; 9:e030353. doi: 10.1136/bmjopen-2019-030353