

Protocole : SPIRIT
DI-CE_ étude principale_ Version 3 du 16/10/2019

PATIENT CONSENT FORM
Main study

The details concerning this intervention research with minimal risks and constraints were communicated to you orally by the investigator and were given to you in writing in a specific information document. After reading this document and after asking all the questions useful to the investigator, if you agree to participate in this research, please complete the consent form below

Title: « SPIRIT Study »

First trimester screening for preeclampsia and intrauterine growth restriction using three dimensional Doppler angiography (SPIRIT): A prospective study in nulliparous pregnant women.

Promoter's name and address : CHRU de Nancy - 29, avenue du Maréchal de Lattre de Tassigny - 54035 NANCY cedex

By signing this consent form, I confirm the following:

- I understood the purpose and the methods 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 time to think before making my decision.
- I must be affiliated to a social security scheme.
- I declare that I am not placed under a legal protection regime for adults (safeguard of justice, curatorship or tutorship) and currently targeted by a procedure tending to this end.

I was clearly informed :

- that I am free to accept or refuse to participate, and I am free to stop my participation at any time during the research. It will not affect the quality of care I receive.
- the purpose of the processing (I was told what this data would be used for) and the recipients of this data. I have noted that my right of access, rectification and opposition provided for by the law of January 6, 1978 relating to data processing, files and freedoms is exercised at any time with the investigator who follows as part of research and who knows my identity.
- that 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
- that the data and the biological samples may be transmitted to other national or international teams (outside the European Union) within the framework of research collaborations, in a form which will not allow my direct or indirect identification.
- that the biological samples can be kept and reused in the same theme
 - that I may at any time request any additional information from the investigator and that any new information arising during my participation and which may modify my decision to participate will be given to me.

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

My consent in no way relieves the investigator and the promoter of all their responsibilities and I retain all of my rights guaranteed by law.

Done in three copies, one of which will be given to me, the second will be kept by the investigator and the third and last will be sent to the Nancy University Hospital (promoter and research coordinator) for verification of the conformity of my inclusion. It will be kept for the time of verification and destroyed by the same person who receives it, who is none other than the CRA research monitor, who, authorized by the sponsor, is authorized to consult my medical file.

To be completed by the patient
Date : ___/___/___
Name : Surname :
Signature of the patient

To be completed by the investigator
Date : ___/___/___
Name: Surname :
I certify that the requirements relating to the information of the person willing to seek and collect their free and informed consent have been met in accordance with the regulations in force.
Signature of the investigator

In case of incapacity to read / write in a participant able to give his consent,

In the absence of reading and / or writing autonomy for Ms, the third person identified below, completely independent of the investigator and the promoter, certifies having personally and faithfully read the participant's notice. information and this consent form and collected his agreement to sign below on his behalf.

To be completed by the third party independent of the investigator and the promoter
Date : ___/___/___
Name of the third person :
Surname of the third person :
Link with the patient :
Signature of the third person :

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