Request to participate in medical research:

IPSISS trial (Implementing preeclampsia screening in Switzerland study)

Dear Miss / Mrs

We are asking you, if you would be willing to participate in our research project.

Your participation is voluntary. All data collected in this research project is subject to strict data protection regulations.

The research project is being carried out by the Women's Clinic of the University hospital of Basel under the direction of Prof. Dr. med. Beatrice Mosimann in collaboration with Dr. med. Leila Sultan-Beyer. If you are interested, we would be happy to inform you about the results from this research project.

We will explain the most important points to you and answer your questions. In order for you to form an opinion we provide you with the most important information. On the following pages, you will find more detailed information.

Why are we carrying out this research project?

- The risk for you to develop preeclampsia during this pregnancy can be detected early in pregnancy. Today, different strategies are used to detect this risk.
- In this research project, we want to define the optimal screening strategy for pregnant women in Switzerland.

What happens if I choose to participate?

- If you decide to participate, your health data will be recorded in a coded registry and a sample of your blood will be stored for further analysis (biobank). For this, we require your consent. No additional follow ups or tests are required due to the trial.

What benefits and risks are involved?

Benefits

- You have nor direct benefit by taking part in this research project.
- Your participation will be of benefit for future pregnant women.

Risks

- No risks arise from your participation.

With your signature at the end oft he document, you attest that you are participating voluntarily and that you have understood the contents of the entire document.

Detailed information

1. Purpose of this trial

Preeclampsia is a pregnancy complication that can cause high blood pressure, maternal organ damage and fetal growth problems. In the first trimester of pregnancy, the risk to develop preeclampsia can be established on the basis of various risk factors. Traditionally, your health and personal medical history are used to determine the risk; however more recently, a screening test, which combines medical history, risk factors, your blood pressure, biomarkers measured in your blood and ultrasound findings has been developed for clinical use. With this trial, we want to investigate which screening strategy provides the best results in the Swiss population and whether additional markers in your blood for example can improve this screening.

2. General information

2-3% of all pregnancies develop preeclampsia with both short- and long-term complications for mother and child. Delivery remains the only therapy, however prevention with low dose aspirin, initiated before 16 weeks of gestation, reduced the risk in high-risk pregnancies.
Pregnancies at risk are classically defined by anamnestic risk factors, but research could demonstrate, that alterations in blood pressure or biochemical or ultrasound markers in early pregnancy are noted in pregnancies that later develop preeclampsia. A combined screening algorithm has been developed to improve early identification of pregnancies at risk.
In Switzerland no consensus exists on how to identify pregnancies at risk. Therefore, we ask for your consent to participate in this trial. We plan to compare the screening strategy applied for your pregnancy with other screening strategies to define the optimal screening strategy for Switzerland.

- We plan to recruit 10'000 pregnant women over the next 5 years from different centres.
- The research project is carried out according to Swiss requirements; all international guidelines will be respected. The responsible ethics committee has reviewed and approved the research project.

3. Process

In each pregnancy the risk to develop preeclampsia is determined either by risk factors or in combined first trimester screening. If indicated, your doctor will recommend low dose aspirin. Your follow-up will continue regularly.
In a central registry we will record data on your risk factors and screening results as well as the outcome of your pregnancy in a coded manner. To obtain your pregnancy outcome we will ask your doctor/hospital for a birth report. Only in the unlikely event that we are unable to obtain a birth report will we contact you for this information. If you agree, the blood sample necessary for screening will be stored for further tests. No additional controls or blood samples arise from your participation.

4. Benefit

There is no personal benefit in participating.

5. Voluntariness and obligations

Your participation is voluntary. If you do not wish to participate in this research project or withdraw your consent at any point, you do not need to justify this decision. Your treatment/care is guaranteed regardless of your decision.

If you are participation in this research project you are asked to:

- inform your doctor about additional treatments prescribed by another doctor.

6. Risks

There are no risks involved in your participation, only data on test results and pregnancy outcomes are recorded in a secure registry.

7. Alternatives

If you do not wish to take part in this project but are open to the possibility to take part in other research projects, please talk to your doctor.

8. Results

There are

1. Individual results, that concern you directly.
2. Individual random results.
3. Objective final results of the whole trial.

In regard of point 1: Your doctor will inform you about all new results and findings that are important for you personally during the course of the project. You will be informed verbally and in writing and can then decide again whether you want to continue participating in the study.
In regard of point 2: Incidental findings are so called „concomitant results“, i.e. results that have not explicitly been researched for, but are found by chance. These can only be expected if you agree to storage of your blood sample in a biobank and analyses are being carried out at a later date. These could be, for example, results of genetic analyses or imaging procedures. In case of incidental findings, you will be informed if these findings are relevant to your health. This means that you will be informed of such findings if a previously unknown disease has been detected by chance or if a disease that has not yet occurred can be prevented. If you do not wish to be informed, please talk to your doctor.
In regard of point 3: Your doctor may send you a summary oft he results at the end of the research project.

9. Confidentiality of data and samples

9.1. Data processing and encryption

For this research project, data about your person and health will be collected and processed, partly in automated form. During data collection, your data will be encrypted. Encryption means that all reference data that could identify you (name, date of birth, etc.) are deleted and replaced by a code. People who do not have access to this key list cannot draw and conclusions about you. The key list always remains in the institution.
Only very few professionals will see your unencrypted data and only to perform tasks within the research project. These persons are subject to the duty of confidentiality. You as a participating person have the right to see your data.

9.2. Data protection and protection of samples

All data protection specifications are strictly adhered to. It is possible that your data must be transmitted in encrypted form, for example for a publication, and maybe made available to other researchers. Data and samples may be sent in encrypted form to another database/biobank as part of this project. The sponsor is responsible for ensuring that the same standards are maintained abroad as in Switzerland. Doctors responsible for follow-up treatment may be contacted to provide information about your health status.

9.3. Data protection in case of further use

Your data and samples might be important for answering other questions at a later stage and/or might be sent and used later to another database/biobank in Switzerland or abroad for investigations not yet further defined. This other database/biobank must adhere to the same standards as the database/biobank for this project. For this further use, we ask you to sign another consent for at the very end of this document. This second consent is independent of your participation in this project.

9.4. Rights of inspections during controls

This research project may be reviewed by the responsible ethics committee and by the project management. The investigator must then disclose your data for such audits. All must maintain absolute confidentiality.

10. Withdrawal
You can withdraw from the research project at any time. In this case, however, the data and samples collected up to that point will still be evaluated in encrypted form. After the evaluation, your data and samples will be anonymised. The key allocation will be destroyed so that no one can find out afterwards that the data and samples originally came from you. This is primarily for data protection purposes.

11. Compensation
There will be no compensation for your participation in this project. No costs will be incurred by you or your health insurance company as a result of your participation.

12. Liability
If you suffer any damage as a result oft he project, the institution or company that initiated the project and is responsible for is implementation is liable. The requirements and the procedure are regulated by law.

13. Funding
The project is mostly paid for by the participating hospitals. Third-party fund are applied for from industry and the state.

14. Contact
You may ask questions about project participation at any time. Also, if you have any uncertainties that arise during the research project or afterwards, please contact:

Dr. med. Leila Sultan-Beyer
Chefärztin Geburtshilfe
Frauenklinik
Kantonsspital Winterthur
Brauerstrasse 15
8401 Winterthur
052 266 27 61

or

Prof. Dr. med. Beatrice Mosimann
Chefärztin Geburtshilfe Frauenklinik Universitätsspital Basel
Spitalstrasse 21
4056 Basel
061 265 90 17

Declaration of consent

Written informed consent to participate in a research project
Please read this form carefully. Please ask it there is anything you do not understand or would like to know. Your written consent is required to participate.

BASEC-number:	ID 2021-01966
Title of the research project:	IPSISS
Responsible institution **(Project management and address)**	Prof. Dr. med. Beatrice Mosimann Chefärztin Geburtshilfe Universitätsspital Basel Frauenklinik Spitalstrasse 21 4056 Basel
Place:	Winterthur
Head of the research project at the study site: Name and first name in print letters:	Dr. med. Leila Sultan-Beyer
Participant: Name and first name in print letters: Date of birth:	

- I have been informed orally and in writing by the undersigned doctor/midwife about the purpose, the procedure oft he research project, possible advantages and disadvantages, and possible risks.
- I am voluntarily participating in this research project and accept the contents oft he written information provided on the above research project. I have had sufficient time to make my decision.
- My questions related to participation in this research project have been answered. I will keep the written information and receive a copy of my written informed consent.
- I agree that the responsible experts of the project management and the ethics committee in charge of this research project may inspect my unencrypted data for testing and control purposes, but under strict observance of confidentiality.
- In case of results that directly affect my health, I will be informed. If I do not wish to be informed, I will inform my doctor.
- I understand that my health-related and personal data (and samples) can only be disclosed in encrypted form for research purposes for this research project. The sponsor guarantees that data protection according to Swiss standards will be observed.
- I may withdraw from participation at any time and without giving reasons. My continued treatment is guaranteed regardless of participation in the research project. The data and samples collected up tot hat point will still be used fort he evaluation of the research project.
- I am informed that the institution has taken out an insurance policy covering damages resulting from the research project.

Place and date	Signature of the participant

Confirmation of the investigator/midwife: I hereby confirm that I have explained the nature, significance and scope oft he research project to the participant. I assure that I will fulfil all obligations in connection with this research project in accordance with the law applicable in Switzerland. If, in the course of this research project, I learn of any aspects that could influence the participant's willingness to participate in the research project, I will inform her immediately.

Place and date	Name and first name of investigator/midwife in print letters Signature of investigator/midwife

Declaration of consent for the use of health-related data and samples for research purposes and for a blood sample (for the reuse of data and samples from this research project)

BASEC number (after submission):	ID 2021-01966
Title of the research project:	IPSISS
Participants name: Name and first name in block letters: Date of birth:	

I give permission or my encrypted (genetic) data and samples from this research project to be further used for medical research. The samples will be stored in a biobank and used for future, as yet undefined research projects for an indefinite period of time.

I understand that the samples are encrypted and the key is stored securely. The data and samples can be sent to other data and biobanks for analysis in Switzerland and abroad if they comply with the same standards as in Switzerland. All legal requirements for data protection are complied with.

I decide voluntarily and can withdraw this decision at any time. If I withdraw, my data will be anonymized and my samples and genetic data will be destroyed. I only inform my doctor/investigator and do not have to justify this decision.

Usually, all data and samples are evaluated as a whole and the results are published in summary. If there is a result that is important for my health, it is possible that I will be contacted. If I do not wish this, I will inform my doctor.

I give permission form y data and samples to be anonymized and understand that in this case I cannot be informed of any random result nor can I withdraw from the research project.

If results from the data and samples are commercialized, I have no claim to share in the commercial use.

Place and date	Signature of the participant

Confirmation of the investigator/midwife: I hereby certify that I have explained to the participant the nature, significance and scope of the further use of samples and/or genetic data.

Place and date	Name and first name of investigator/midwife in print letters Signature of investigator/midwife