# Evaluation of PArental and neonatal streSS during the perinatal period and its effect on prematurity (PASS)

Dear Sir or Madam, dear parents

**Who we are**
We are the Newborn research team of the Department of Neonatology of the University Hospital and University of Zurich
Project leader: Dr. med. Dr. sc. nat. Tanja Restin, Senior Physician
Project sponsor: Prof. Dr. med. Dirk Bassler, Head of the Department

**Why are we contacting you**
We would like to invite you to support medical research

In the framework of our research project **PASS** we would like to evaluate stressful and protective factors of parents shortly before and after birth. In order to perform this, we would need health data and fingernail cuts of you and your child after birth. Therefore, we would like to ask you, whether you would kindly provide us with your fingernail cuts and health.

In order to be allowed to further analyze your material and data, we need your informed consent. Please read this information and sign the form if you agree. You can send your Declaration of Consent together with your nail cuts back to us.

## General information

### 1. Aim of the project
With this project we would like to assess whether and to what extent the life situation of parents may influence their experience of self-efficacy and stress during pregnancy and after birth. In addition, we would like to investigate how the newborn baby with all his or her characteristics including any potential disease might influence the health-related quality of life of his or her parents.
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### 2. Selection
Any parent who is older than 18 years and is expecting one or several newborn babies within the following months is welcome to participate can be included. It does not matter whether it is the first or a consecutive child. Parents who are suffering from severe nail biting or nail diseases or who are receiving high-dosage corticosterone cannot be included in the study. Only parents who understand the study information can participate.

### 3. Project details
This project is being conducted at the University Hospital of Zurich and the University of Zurich in order to improve family-centered care at the Department of Neonatology. It is well-known that the birth of a child changes the daily routine of its parents significantly. With our questionnaire and nail analyses we would like to learn find out more about any potential stress and protecting ~~on~~ factors for parents during the perinatal period. Our long-term goal is to support parents as a health-care team in a way that the whole family can achieve good quality of life, even if the course of pregnancy and birth might have been difficult. This project is conducted in accordance with Swiss law. The ethics committee in charge has reviewed and approved this project.

### 4. Study-Workflow

Study participation includes responding to a questionnaire during the 20-32th week of pregnancy, within the first month and 2-4 month(s) after birth. We explicitly would like to ask both parents independently, however, participation of one single parent is also possible. Each questionnaire should take about 15-20 minutes to answer. In addition, we would like to analyze the nail cuts (leftovers of normal nail cuts) of both parents (during pregnancy, one month and 2-4 months after birth) and their child (comprising the first 6 nailcuts after birth). Altogether parents will therefore invest about 1.5 hours for this study over a time period of 6 months. Questionnaires and material for the fingernail cuts will be provided accordingly.

**5. Benefit**
You do not have a direct benefit through the participation in this research project.

**6. Rights**
You will only need to provide us with your health data and/ or fingernail clippings for this research project, if you want to. Nobody is allowed to urge or push you. Your decision will neither affect your medical treatment nor the medical treatment of your child. You do not have to justify why you do not want to participate or why you might want to withdraw your participation at a later time point. Please contact the study team to do so.

**7. Obligations**
As participant it is needed that you consider the requirements of the project lead and return the preferably completed questionnaire back to us.

**8. Risks**
Participation in this project does not bear any risks

**9. Study results which are important to you**
Results from this research project that affect your health or the health of your child will be provided, if possible. However, you can also choose not to receive such a notification if you do not want to know these results. Knowledge about certain diseases can be a disadvantage if you would like to negotiate a supplementary insurance. Please inform the contact person below if you do not wish to be informed.

**10. Data confidentiality**
We will keep all your data strictly confidential. For this research project, your personal and medical information, as well as your child's information will be collected. Only very few medical professionals will see your uncoded data and only to perform tasks related to this research project. When collecting data for the purpose of this study, the data will be coded. Coding means that all reference data that could identify you or your child (name, date of birth) will be deleted and replaced by a code. The code list will always remain within the research team stay at the University of Zurich. Those people who do not know the identification key will not be able to draw any conclusions about you. In case of a publication the summarized data is therefore also not traceable to you as individual. Your name will never be published online or in a publication. Sometimes for publication, there is a requirement in a scientific journal that individual data (so called raw data) must be submitted. In such a case, the data is always coded and thus also not traceable to you as a person. All persons who have access to your data within the framework of this research project are subject to the duty of confidentiality. The requirements of data confidentiality are observed. You as a participant always have the right to access your personal data at any time.

**11. Data safety in case of further use**
Your data and nail samples could be relevant for further research questions in the future. For this purpose they could be transferred into another data collection in Switzerland or abroad. This data and sample storage has to have the same safety

standards as ours. If you agree on further use, you have to sign a second informed consent form. This second consent is not dependent on the participation in this project.

**11. Withdrawal**
You can withdraw your participation in this research project at any time. The gathered data up to this time will be analyzed to prevent the research project from losing value. After the analyzation, your data will be anonymized which means that your code will be destroyed so that nobody can find out from whom the data originated.

**12. Liability**
If you suffer any harm as a result of this research project, the “Versicherung für klinische und nichtklinische Versuche” by the Zürich Versicherungs-Gesellschaft AG (Police Nr: 14.970.888) is liable. The conditions and the procedure are regulated by law.

**13. Funding**
This project is funded by the Departement of Neonatology, University Hospital Zurich and supported by a grant from the Hartmann Müller foundation.

**14. Compensation**
We will offer free samples from various manufacturers as a small compensation. The products do not reflect a buying incentive and the research project is independent from these manufacturers.

**15. Contact person**
If you have any uncertainties or worries during or after the project you can call one of these contact persons any time. Leader at project site: Dr. Tanja Restin, Frauenklinikstr. 10, 8091 Zürich, +41 44
255 53 45, tanja.restin@usz.ch. You can also call 044-255-11-11 and will be connected with the senior physician on duty at the Department of Neonatology.

**Declaration of consent for further use of biological material and personal data for a research project in an uncoded form (Art. 28 HFV)**

I hereby consent to the further use of samples and other data of mine and my child relevant to this project obtained from medical treatment or otherwise in an uncoded form for the research project mentioned below.

**BASEC-Number** ID 2021-00464

**Title of the Project** **Evaluation of PArental and neonatal streSS during the perinatal period and its effect on prematurity (PASS)**

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|---|---|
| **Responsible institution** | Newborn Research Zurich, Department of Neonatology, University Hospital and University of Zurich, Frauenklinikstr. 10, 8091 Zurich, Switzerland |
| **Place of Implementation**: | University Hospital and University of Zurich |
| **Responsible Investigator at the Study location** | Dr. med. Tanja Restin |

**Participant:**
Name and first name in block letters:
Date of birth:
☐ female ☐ male

**Name of the participating child**
Date of birth
☐ female ☐ male

I hereby confirm that

- I have received the study information that belongs to this informed consent form
- I am older than 18 years
- Do not suffer from severe nail baiting or a nail disease
- I do not need any high dose cortisone-therapy
- I have been adequately informed about the storage and further use of my biological material and personal data for the above mentioned research project in uncoded form
- I had the opportunity to ask any questions which could be answered to my satisfaction
- I have been informed that my consent is voluntary and in particular, that I will not suffer any disadvantages if I consent or refuse to participate
- I know that I can withdraw this consent at any time and that I do not need to give any reasons for doing so
- I know that I will be informed about results relevant to me. If I do not wish to be informed, I will inform the contact the person named above.
- I know what will happen with the material and data before withdrawal of the consent

Location, Date | Signature of the participant or his/her legal substitute

**Declaration of consent for further use of biological material and personal data for a research project in a coded form (further use of data and samples from this study)**

**BASEC-Number** ID 2021-00464

**Title Evaluation of PArental and neonatal streSS during the perinatal 12 period and its effect on prematurity (PASS)**

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| **Responsible institution** | Newborn Research Zurich, Department of Neonatology, University Hospital and University of Zurich, Frauenklinikstr. 10, 8091 Zurich, Switzerland |
| **Place of Implementation**: | University Hospital and University of Zurich |
| **Responsible Investigator at the Study location** | Dr. med. Tanja Restin |

**Participant:**
Name and first name in block letters:
Date of birth:
☐ female ☐ male

**Name of the participating child**
Date of birth
☐ female ☐ male

I allow that my coded data and samples deriving from this study may be further used for medical research. The samples will be stored in a biobank and may be further used for future study projects during an unlimited time frame. I understand that the samples will be coded and the key code will be stored securely. Data and samples can be sent around Switzerland or the world if the data and biobank-standards are the same as in Switzerland. All legal guidelines for data protection will be observed. I decide voluntarily and can withdraw this decision at any time. If I withdraw, my data will be anonymized and the remaining samples will be discarded. I only inform my study representative and do not have to justify my decision. Normally, all data and samples will be analyzed jointly and data published together. If there is a result which might be important for my health I might be contacted. If I do not want this, I will contact the study team.
I allow that my data and samples will be anonymized and I understand that in this case I will not be able to be informed about results nor is it possible to withdraw the participation. If there might be a commercialization, I will not be able to claim any profit deriving from the use.

Location, date

Signature of participant
(legal representative)