HELSE STAVANGER
Stavanger universitetssjukehus

Universitetet i Stavanger

Version 4.2 Stavanger 25.10.21

DO YOU WANT TO PARTICIPATE IN THE RESEARCH PROJECT «NEWBORNTIME»?

PURPOSE OF THE PROJECT AND WHY YOU ARE ASKED

Will you be giving birth at the Stavanger University Hospital? Then this is an invitation to participate in the «NewbornTime» research project. The purpose of NewbornTime is to develop new technology for automated video analysis where artificial intelligence (AI) is used to record the time of birth and the treatment the child received, and use the data for research, teaching and quality improvement. The overall goal of the project is improved neonatal care.

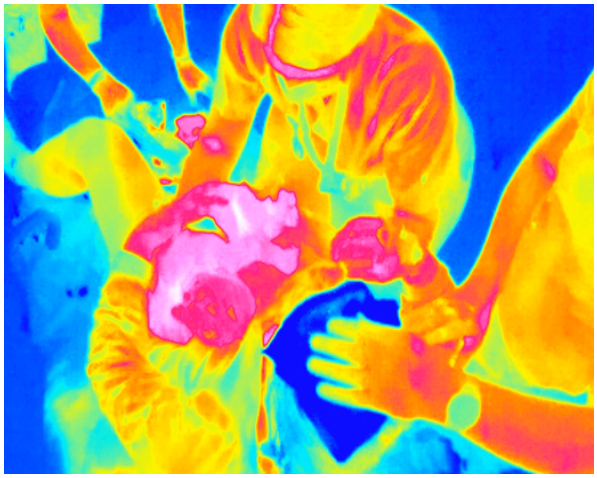
The project is linked to the ongoing project "Better monitoring of newborns after birth and resuscitation" at SUS.

Approximately 5% of newborns require breathing assistance to cope with the transition from fluid-filled lungs in the mother's womb to breathing on their own. To avoid injury, breathing assistance must starts quickly.

Therefore, this project will develop a novel newborn timeline, with automated registration of the time of birth and the treatment given until the baby breathes on its own. The timeline documents what happened so that healthcare professionals can learn; it can detect deviations and it can identify areas where there is a need for better routines or training.

WHAT DOES THE PROJECT MEAN FOR YOU?

As a mother, you will not be affected by the project. You are receiving this information in advance so we can ask you for consent to use your data in our research and teaching.



This is how we collect data:

The exact time of birth is recorded using so-called thermal ("heat-detecting") cameras that can detect temperature differences. There is no radiation from those cameras and the cameras do not detect sound. When video recordings are made with a thermal camera, you can see that there are people on the video but it will not be possible to recognize who they are. See the example picture taken of a birth at SUS.

Newborns who need breathing assistance are moved to a treatment room where regular video and audio are recorded from the treatment station. In the video, only the employees' hands and the newborn are visible. In this room there is also a thermal camera to record the number of people participating in the treatment.

For a complete and accurate description of the newborn timeline, SUS will use relevant information from the birth journal and the child's journal together with the video recordings. This information will be used for teaching, medical research and technology development.

We also request permission to use video and photos (similar to the one shown here), where date and time have been removed, along with newborn timelines and information from the birth journal in teaching and for quality improvement.

ADVANTAGES OF PARTICIPATION

The medical treatment provided is exactly the same and is not affected by the project. Therefore, there are no advantages or disadvantages for the mother before the technology is developed and put into use.

PARTICIPATION IS VOLUNTARY AND YOU CAN WITHDRAW YOUR CONSENT

Participation in this project is voluntary. If you wish to participate, you must provide your consent. Also, you may withdraw your consent at any time without the need to provide a reason. There are no negative consequences for you or your treatment if you choose not to participate or later withdraw consent. If you withdraw your consent, your health data will not be further researched. You may also demand that your health information stored in the project be deleted within 30 days. The right to demand deletion does not apply if the information has been anonymized or already published. Access can also be restricted if your health information has been included in the analysis already performed.

WHAT HAPPENS TO YOUR DATA?

We take your privacy serious, and we have the necessary legal approvals. All information will be de-identified and the data will be protected using secure encryption and access control. The videos will only be used as described in the project, and only project staff will have access to the video recordings. Data security for video recording, storage and analysis complies with current GDPR legislation.

The information registered about you will only be used as described under the purpose of the project and is expected to be used until 2029. Any extensions in use and storage time can take place only after approval by the Regional Ethics Committee (REK) and other relevant authorities. You have the right to know what information is registered about you and the right to have any errors in the information corrected. You have the right to access information about the security measures installed to protect personal information in the project. You can file a complaint about the processing of your information to the Data Inspectorate and the institution's privacy representative.

The information about you will be kept for five years after the end of the project for control reasons.

INSURANCE

Insurance for hospital treatment follows the Patient Injuries Act.

FOLLOW-ON PROJECTS

If there is a follow-up project, a new request for consent will be sent to you for letting your child participate in the study.

COSTS

There is no fee or compensation for participation in the study. The project has received financial support from the Research Council of Norway, Idella foundation and Helse Vest. Laerdal Medical and BitYoga are partners in the project.

ETHICS

The Regional Committee for Medical and Health Research Ethics has made a research ethics assessment and approved the project, REK number 222455.

On behalf of the University of Stavanger, NSD - Norwegian Center for Research Data AS has assessed that the processing of personal data in this project is in accordance with the privacy regulations, NSD reference number 816989.

MORE INFORMATION

If you have questions regarding consent or the project, you can get more information during the ultrasound examination, by contacting the person responsible for the data collection or by reviewing the project's website for participants: www.uis.no/newborntime/participant

CONTACT INFORMATION

Responsible for «NewbornTime» at the University of Stavanger is the Project Leader Prof. Kjersti Engan, kjersti.engan@uis.no

Responsible for data collection is the Stavanger University Hospital and project manager at SUS is Chief Physician Siren Rettedal, siren.irene.rettedal@sus.no

Norwegian Center for Research Data (NSD): personverntjenester@nsd.no

Privacy officer at UiS: personvernombud@uis.no

Data Inspectorate: postkasse@datatilsynet.no

WITHDRAWL OF CONSENT

Before / after birth: Consent can be withdrawn using the same digital platform in which consent was originally granted.

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Laerdal
helping save lives

- ☐ I (mother) agree to participate in the project and for my collected data to be used FOR RESEARCH as described.

- ☐ I (mother) agree that my collected data can be used FOR TEACHING and QUALITY IMPROVEMENT.

This QR code leads to the digital platform where consent can be granted or withdrawn: