

Information for participating in scientific research

Parent Consent for Child

1. Introduction

Dear Sir/Madam,

We would like to ask for your permission to collect data for research on ventilatory support. In this letter you can find information about the research.

2. What is “ventilatory support”?

Recently, your child has been admitted to the pediatric intensive care unit. During this admission, his or hers breathing has been assisted by a ventilator, because your child was not able to breath itself. During ventilatory support a 'ventilator' pushes air through a small tube in the nose or mouth. This small tube leads the air in- and out of the lungs.

3. Why are we doing this study?

Ventilatory support is often a life-saving therapy. However, it may also cause harm. Studies on the practice of ventilatory support in children are lacking. This study will investigate practice of ventilatory support in children all around the world, to help us improve treatment.

4. What is the purpose of this study?

The aims of this study are to;

1. describe the practice of ventilatory support in children admitted to the intensive care unit; and
2. identify which ventilator settings are associated with outcomes.

5. What Are We Asking Consent For?

We are asking for your permission to collect data of your child and use this for this research. Participation in this study means that you child will receive treatment as usual, no additional interventions or changes in treatment will be performed for this study. During the period that your child is admitted to the ICU, medical data is recorded from the patient's record system, including medical history, patient characteristics such as age, sex, height, weight, daily ventilation data with a maximum of 3 days, and outcome data at day 28. All collected information will be transcribed and will be used confidentially. The data will be anonymized and only the anonymized data will be shared and centrally stored on secured servers in the Amsterdam UMC in the Netherlands.

6. Is it safe to be in this study?

Yes, it is safe, there are no risks and discomforts. Only data as part of standard routine care will be collected, no research related interventions will take place. The treatment of your child will remain unchanged.

7. Are there (financial) benefits from being in the study?

There are no direct (financial) advantages or disadvantages by participating with this study. However, this research will help doctors improve ventilatory support treatment.

8. How many participants will be in this study?

This is an international multi-center study being done in many countries worldwide. We anticipate that 25.000 children will participate with this study.

9. Can I choose to leave the study?

Yes, it is your choice to decide if your child takes part of the study, participation is absolutely voluntary. And if you, for any reason, decide at a later time-point that the gathered data should not be used for scientific research, it will not impact their treatment and the collected data will not be used. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study. If you decide to leave the study, you can contact a member of the study team.

10. Conclusion of the Research

Your child's participation in the study will end if:

- The observation period, duration of ICU stay with a maximum of 28 days, is completed; or
- You decide that the collected data cannot be used for medical research.

11. Use and Storage of Your Data

For this research, we will collect data out of the electronic patient system. The data will be anonymized. Only the anonymized data will be shared and centrally stored on secured servers in the Amsterdam UMC in the Netherlands. Additionally, in reports and publications about the research, the data will not be traceable back to you. Information about this research is also included in a registry, clinicaltrials.gov.

Retention and Use of Data for Other Research

After the completion of this research, the data will be stored for 15 years. This data may still be relevant for other scientific studies in the field of ventilatory support. You can indicate on the consent form whether or not you agree to this. If you do not agree, you can still participate in the current study.

Withdrawal of Consent

You can always withdraw your consent, both for this research and for future research.

More Information About Data Processing Rights

If you have questions about your rights, you can contact

12. Do you have questions?

If you have any questions, please ask the doctor or the local researcher. If you have any complaints about the research, you can discuss them with the researcher or your attending physician. If you prefer not to do so, you can contact the complaints committee of your hospital. All contact details can be found in attachment A.

13. Signing the Consent Form

Once you have had sufficient time for consideration, you will be asked to decide whether we may use your child's collected data for scientific research. If you grant permission, we request you to confirm this in writing on the accompanying consent form. Your written consent indicates that you have understood the information and agree to the use of collected data for research purposes. The signed document will be retained by the attending physician, and you will receive a copy or a second copy of this consent form.

Thank you for your attention.

14. Attachments to this Information

- A. Contact details**
- B. Participant Consent Form**

Attachment A: Contact Information for [HOSPITALNAME]

Local investigator

Name	
Department	
Phone number	
Email address	

Independent expert

Name	
Department	
Phone number	
Email address	

Attachment B: Participant Consent Form

PROVENT-PED – Practice of ventilation in critically ill pediatric patients

I have been asked to give consent for the use of my child's data collected for this research.

- I have read the information letter and had the opportunity to ask questions. My questions have been adequately answered, and I had enough time to decide whether to grant permission for the use of my child's collected data.
- I have the right to withdraw my consent for the use of my child's data for this research, and if applicable, future research at any time, without having to provide a reason.
- I am aware that, for the monitoring of the research, some individuals may have access to all of my data. Those individuals are listed in this information letter. I consent to this access by these individuals.
- I consent to the retention of my child's for 15 years after the conclusion of this research at the research site.
- I consent to the use of my child's collected data for this research in the manner and for the purposes outlined in the information letter.
- In the event that I am not physically able to sign the form, I orally give consent for my legal representative to sign the form on my behalf.

Tick the following boxes if it applies to you:

- I grant permission to use my child's data for future research in the field of ventilation.
- I grant permission to use my child's data to participate in this research and share the data with the coordinating research center (Amsterdam UMC in the Netherlands).

Name participant or legal representative:

Signature:

Date: __/__/____

- The research representatives declares that they have fully informed this research participant about the mentioned study
- The research representative declares that if any information arises during the research that could potentially affect the participant's consent, they will notify them as soon as possible.

Name research representative:

Signature:

Date: __/__/____
