Information for participating in scientific research

Consent for Child (12-15)

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1. Introduction

Dear _____,

We would like to ask you if you want to participate with research on 'ventilatory support'. We will also ask your parents' (or legal guardian's) for permission. In this letter you can find information about the research. Together with your parents, you can decide whether you would like to participate or not.

2. What is "ventilatory support"?

Recently, you have been admitted to the pediatric intensive care unit. During your admission, you're breathing has been assisted by a ventilator, because you were not able to breath yourself. During ventilatory support a 'ventilator' pushes air through a small tube in your nose or mouth. This small tube leads the air in- and out of your 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. 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. Your treatment will remain unchanged.

6. 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.

7. When is your participation in this study done?

Your participation in the study will end if:

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

10. What will we do with the information we gather about you?

For this research, we will collect data out of the electronic patient system. The data will be anonymized, so no one will be able to identify you, except for the local investigators. 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, your data will be stored for 15 years. Your data may still be relevant for other scientific studies in the field of mechanical ventilation. 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 ….

11. Do you have questions?

If you have any questions about this study feel free to ask your parents, 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.

12. Signing the Consent Form

Once you have had sufficient time for consideration, you will be asked to decide whether we may use your 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 reading this letter. We hope you would like to participate with this research.

13. 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 data collected for this research.

- I have read the information letter and had the opportunity to ask questions. My questions have been answered, and I had enough time to decide whether to grant permission for the use of my collected data.
- I understand I have the right to withdraw my consent for the use of my 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 data for 15 years after the conclusion of this research at the research site.
- I consent to the use of my 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 data for future research in the field of ventilation.
- ○ I grant permission to use my 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: ___/___/_____
