The Children's Hospital of Philadelphia®

Consent Form for Trainees and Frontline Providers

Study Title: Improving safety and quality of tracheal intubations in neonatal ICUs

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You may be eligible to take part in a research study. The information that will be discussed gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating. The word "we" means the study doctor and other research staff.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you are a trainee or frontline provider in the NICU.

What is the purpose of this research study?

The purpose of the study is to determine the efficacy of video coaching training for neonatology trainees and frontline providers on tracheal intubation procedural outcomes in neonatal ICUs.

What is involved in the study?

If you agree to take part in this study, we will ask you to answer a few questions about your years of experience and training performing tracheal intubation.

You might be asked to confirm your actual participation in tracheal intubation in the neonatal ICU by study team.

The intubation events that you participate in will be subsequently analyzed as part of the research.

What are the risks and benefits of this study?

As with any study involving collection of data, there is the possibility your confidentiality information will be shared with others. Every precaution will be taken to secure your personal information to ensure confidentiality. All data will be recorded with subject ID.

Your decision to participate will not have any effect on your performance evaluation or employment status.

The potential direct benefit for the trainee study participation is to receive a standardized education from frontline providers when performing a tracheal intubation procedure using a video laryngoscope.

Do you need to give your consent in order to participate?

By telling us that you agree, you are indicating that you have had your questions answered, and you agree to take part in this research study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you should receive.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What about privacy and confidentiality?

We will do our best to keep your personal information private and confidential. Specifically we will not collect your personal identifiable information. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. People from oversight agencies and organizations such as the Department of Health and Human Services, Office for Human Research Protections may also look at your study records.

The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals.

By law, CHOP is required to protect your private information. The investigator and staff involved with the study will keep your private information collected for the study strictly confidential.

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information can be shared for:

- your medical treatment and/or for use by your insurance company;
- other purposes not connected with this research.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project. Also, the US Food and Drug Administration (FDA) may need information.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse or communicable diseases.
- Some information from this study must go in your medical record.

- Your information and biological samples may be shared for other research.

Financial Information

The study is funded by the National Institute of Health (NIH).

Will you be paid for taking part in this study?

No

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Nishisaki at 215-590-5505. You may also talk to your site leader if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

Documentation of Verbal Consent to Take Part in this Research Study

The research study and consent form have been explained to you by:

_____
Name of Subject

The research study and consent form was explained to:

_____
Person Providing Consent

The person who provided consent confirmed that all of their questions had been answered and they agreed to their participation in this research study.

_____
Person Obtaining Consent

_____
Signature of Person Obtaining Consent

_____
Date