COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title: **Randomized Trial of Endotracheal Tubes to Prevent Ventilator-Associated Pneumonia – PreVent 2 Study**

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Research Study Summary:

- You or your family member has been enrolled in a research study. "You" through this document refers either to yourself, as the subject, or the person for whom you are the legally authorized representative.
- You were enrolled in this study because you had a critical injury requiring the use of a breathing tube (endotracheal tube). Because the breathing tube is needed to connect you to the breathing machine, you are in the Intensive Care Unit (ICU) at Yale New Haven Hospital (YNHH). We are now asking you if you want to stay in the study.
- The purpose of this research study is to evaluate two standard breathing tubes that can be used in patients who are on breathing machines. Both breathing tubes are cleared for use by the Food and Drug Administration (FDA), and are regularly used in hospital settings. We are doing this study because we want to find out if one of these two breathing tubes is better at preventing complications that can be associated with the breathing machine, such as pneumonia, and therefore improving quality of life of patients.
- If you agree to continue participating in the study, the research team will follow your care daily during your hospital stay. There is one follow-up visit at 6 months that will take 60-90 minutes to complete. It can be done at the hospital or at home.
- Both breathing tubes carry the same types of risks.
- The study may have no benefits to you. There is some evidence that the study breathing tube may be effective in preventing pneumonia. It is not possible to know now if the study tube will prevent pneumonia compared to the usual breathing tube.
- There are other choices available to you outside of this research. You may choose to no longer be in this study. While the breathing tube that is in place will not be exchanged, we would stop collecting any data as part of the study.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

Sometimes patients who have breathing tubes and need breathing machines experience problems like pneumonia. Researchers are conducting this study to evaluate two breathing tubes that can be used in patients who are on breathing machines. The two breathing tubes we will study are:

1. PVC-ETT (Basic tube)
2. EVAC-PU-ETT (Study tube)

Both breathing tubes are cleared for use by the Food and Drug Administration (FDA), and are regularly used in hospital settings.

We are doing this study because we want to find out if one of these two breathing tubes is better at preventing problems associated with the breathing machine, such as pneumonia, and therefore improving quality of life of patients.

We plan to enroll 1,074 subjects in this study.

Who is paying for the study?

The National Heart, Lung and Blood Institute (NHLBI), which is part of the National Institute of Health (NIH).

Yale University is being compensated by the funder to conduct this study. This is to pay for the study supplies, the time involved on the part of the investigator(s), study staff, and also to compensate the study participants to attend the 6-month follow up visit. You may freely discuss this with your physician and the investigator if you have concerns.

Your study doctor and the research staff have no financial involvement with the funder and are not being paid directly by the funder for conducting this study. However, they may have travel expenses covered by the funder to attend scientific meetings.

What is the study about?

The purpose of this study is to look at two different types of breathing tubes to see if one of them is better at preventing pneumonia. Both breathing tubes are cleared for use by the Food and Drug Administration and are regularly used in clinical care.

At the tip of both breathing tubes there is a balloon (called “cuff”) that is inflated with air to prevent fluids from leaking into the lungs. The basic breathing tube has a cuff made of a polyvinylchloride (PVC) material. The study breathing tube has a cuff made of a polyurethane (PU) material. In addition, the study tube has a side channel that can be connected to a suction device and allows continuous suction of saliva from the back of your throat before it can leak into the lungs.

We are doing this study because we want to find out if one of these two breathing tubes is more effective at preventing pneumonia than the other.

What are you asking me to do and how long will it take?

We tried to contact you for consent as soon as possible after your admission to the ICU. However, if you were too sick for us to talk to you, or if we could not find one of your relatives, then we have already started the study. You needed a breathing tube for your clinical care, and you received one of the two breathing tubes. We may have already collected some data from your medical record.

You will have standard medical and surgical care for your illness. If you decide to stay in this study, you will also have the following additional procedures performed while you are in the hospital. These procedures will only be done because you are in the study:

- If you have the breathing tube in place with the side channel, it will be connected to a suction tube to remove saliva from the back of your throat. The port will be kept on suction for most of the time while the tube is in place.
- The research team will follow your care daily to see if you develop symptoms of pneumonia. When your breathing tube is removed, we will review your medical record to see if there is any evidence of injury or complications.
- In addition, the study team will also review documentation in your medical record (such as lab and diagnostic tests and providers' notes) on a daily basis. We will record the findings from our review into our study documentation. We will record details about your past medical history and your current illness from the medical record. We will also record the time you spent on the breathing machine, time in the ICU, and in the hospital.
- Six months after you were enrolled in the study, a study follow-up appointment will be scheduled. At this visit, we will interview you with questionnaires about different areas of your life since you were enrolled. These questionnaires ask about your quality of life and cognitive function (mental ability). This appointment can be scheduled to take place at YNHH or at your residence, whichever is more convenient. The visit should take approximately 60 to 90 minutes to complete.
- We will check your medical record to know if you experienced adverse events during the six-month follow up. Primary care providers or specialists may be contacted to inquire about adverse events.

If you decide not to stay in the study, we will not collect any more data from your medical record. We will keep the medical record data we have already collected.

What are the risks and discomforts of participating?

You received a breathing tube as part of your care for a serious injury or illness. Some people in your condition received a study breathing tube model that is not currently used at YNHH, while others in your condition received the basic breathing tube. Both breathing tubes are FDA-cleared and used in many hospitals and carry the same types of risks. Because you required a breathing tube for your clinical care, we expect you will be exposed to the same clinical risks if you were not in this study. These are known clinical risks and not a result of participation in this

research study. There are no known increased medical risks related to this study. There may be some risks that the investigators do not yet know about.

This study will look at all patients that received the study tube and basic tube to see if they have evidence of injury to the vocal cords and lower airway. We will carefully monitor all patients in this study and record complications that related to the breathing tubes.

We will have access to your medical records throughout the duration of the study. Whenever personal information is collected, there is always the risk that someone who is not supposed to see the information will see it. However, we will try to make sure that this doesn't happen.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study. The results of research tests will not be made available to you because the research is still in an early phase and the results are not known yet.

How can the study possibly benefit me?

There is some evidence that the study breathing tube may be effective in preventing pneumonia. It is not possible to know now if the study tube will prevent pneumonia compared to the standard breathing tube.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of whether or not the study tube will prevent pneumonia compared to the standard breathing tube. This study will evaluate if preventing pneumonia improves the quality of life and mental abilities six months after the placement of the breathing tube.

Are there any costs to participation?

You will not be billed for the costs of any services or procedures that are required by the study but are not considered part of your regular treatment.

If you take part in this study, you will not have to pay for any services, supplies, study procedures, or care that are provided for this research only (they are NOT part of your routine medical care). However, there may be additional costs to you. These can include costs of transportation and your time to come to the study visits. You or your health insurance must pay for services, supplies, procedures, and care that are part of your routine medical care. You will be responsible for any co-payments required by your insurance.

Will I be paid for participation?

You will receive $100 as compensation for participation upon completion of the 6-month follow up assessment.

We will use a Bank of America pre-paid debit card to provide the payment for taking part in the study. We will have to share your name, address, and telephone number with Bank of America for ePayments. You will receive a card in the mail with the payment. You will need to activate the card over the phone. Instructions will be provided on how to do that.

You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?

You may choose to not to be in this study. However, if you have the breathing tube in place with the side channel, the breathing tube will not be exchanged. The decision to continue using the suction port will be left at the discretion of your care team. Clinically, we would continue to monitor you for any concerns. We would stop collecting any data that would be considered a part of the study.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we must do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

Your research data will be stored on a secure server. Your research data will be identified by a unique study identification number. The study data entry used by YNHH research staff will be secured and password protected, and research materials will be stored in locked cabinets. At the end of the study, all study databases will be de-identified and archived on a secure server.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the

Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records, including surveys and questionnaires
- Records about phone calls made as part of this research

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about the devices involved in this research.
- The funder of this study, The National Heart, Lung and Blood Institute and the funder's representatives.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Heart, Lung and Blood Institute, which is funding this

project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Miriam Treggiari, at the Yale University, Department of Anesthesiology, PO BOX 208051 New Haven, CT 06520-8051.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

The investigator may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study funder NHLBI.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

What will happen with my data if I stop participating?

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your information, but the material will not be destroyed, and we will continue to use it for research.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Clinical Study Manager, Michael Kampp, at 203-737-5118.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date
Legally Authorized Representative Printed Name	Legally Authorized Representative Signature	Date
Relationship to the Participant		
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date
Witness Printed Name	Witness Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.