NCT04195178
Understanding the Cognition and Decision Making of Community Anesthesiologists
June 16, 2025

Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Weinger, Matthew B. **Revision Date:** December 2, 2019
Study Title: Understanding the cognition and decision making of community anesthesiologists in their management of end-of-case neuromuscular blockade: A mixed methods study
Institution/Hospital: Vanderbilt University School of Medicine

This informed consent document applies to: clinically active anesthesiologists who volunteer to participate in a research study.

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You are free to withdraw from this study at any time until the end of the study. After that time, all study materials will have been completely de-identified and it will not be possible to distinguish your data from that of other participants. In the event that new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision as to whether or not to continue your participation in this study.

1. **Purpose of the study:**

   The purpose of the study is to conduct a prospective observational study to better understand the decision making understand decision-making during emergence and around extubation.

   You are being asked to participate in this research study because you are a clinically active anesthesia provider. If you are attending a simulation course, you can take part in the research study before or after the scheduled time of your simulation course or on a different day, at a mutually convenient time.

   This research study is not affiliated with and has no bearing on any simulation course, which you may have attended today, if applicable, nor its timing, quality or results. Your study related answers are independent of any simulation training course in which you participate and will be stored separately. There are no right or wrong answers in this research study.

   About 48 anesthesiologists will participate in this study. About 16 of them will be studied at Vanderbilt University Medical Center.

2. **Procedures to be followed and approximate duration of the study:**

   If you agree to participate in this study you will:

   - Complete an online screening survey about your training, experience, and current clinical activity.
   - Complete an online demographic survey about your clinical background, training, and experience.
   - Read and respond to clinical vignettes regarding patient care.
   - Complete an audiotaped interview about your clinical decision-making.

   Your participation in this study will take approximately 75 minutes.

3. **Expected costs:**

   There are no costs to you for taking part in this research study.

4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

The risks to participants in this study are minimal. The only credible risks might be psychological stress or breach of confidentiality. The psychological risks to participating in this study are no greater than that from participating in clinical training. To protect your identity, your study data will be assigned a code. The key that links the code to you will be accessible only to the study team and will be destroyed at study closure.

While there are discomforts and inconveniences associated with any research study, the risks, discomforts, and inconveniences in this study are expected to be negligible.

5. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. Information gathered may help us to develop educational programs in the future.

b) The benefits you might get from being in this study. You will not benefit from participating in this study.

6. Compensation for participation:

We may ask for your Social Security number and address before you are compensated for taking part in this study.

You will be paid $300 by check, which may take 4 to 8 weeks to be issued and disbursed to you, if you complete participation in this study. This amount may be taxable and will be reported to the Internal Revenue Service (IRS).

7. Circumstances under which the Principal Investigator may withdraw you from study participation:

At the discretion of the principal investigator, you may be withdrawn from this study at any time for the following reasons: the screening survey findings indicate that you are not eligible,.failure to follow instructions, the investigator decides that continuation could be harmful to you, the study is cancelled, or other reasons.

If you are withdrawn from the study, you will be told the reason.

8. What happens if you choose to withdraw from study participation?

You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights or benefits to which you are entitled.

Your decision will not affect your standing as a clinician or your experience in any training course you may have attended, if applicable. If you decide to withdraw from the study at any time, please notify Dr. Weinger. If you decide to withdraw, your data will not be retained.

9. Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact **Matthew Weinger, MD at 615-936-6598 from Monday through Friday, 9AM to 5PM.**

Dr. Weinger may also be reached by email at: **matt.weinger@vumc.org.**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. All data will be kept strictly confidential and will not be shared with any person who is not part of the research team except as required by law. The confidentiality and security of all research data and of the video recordings will be maintained through multiple means. De-identified data will be retained for 7 years after study completion.

A. No data associated with transcribed audio recordings will contain participant, date, or site identifiers, only random study code numbers and site accession numbers.
B. The master list that links participant identity and the random code numbers will be stored in a password protected database accessible only to study staff.
C. No participants' identities will be divulged outside the research team including in publications or presentations.
D. All electronic study data will be transferred to computer systems and/or networks that require authorized user name and password authentication for access.
E. Research records that contain identifiable information (e.g., consents) will be kept in locked storage units in locked rooms to which only authorized researchers will have access.
F. Each study site's servers and audio storage locations will be in secure locations not readily accessible except by authorized personnel.
G. Audio recordings will be collected, from study sites to the Coordinating Center (Vanderbilt) only via authorized secure methods (i.e., secure server).
H. Only specific research personnel will have access to review the audio tapes, and in a very proscribed secure manner.
I. Audio recordings will not be made available to participants for their own use.

14. Privacy:

We will take several precautions to achieve the greatest degree of privacy for participants possible. All participants will be formally instructed not to discuss the study with anyone outside of the course. Researchers are similarly expected to maintain confidentiality as to the performance of course participants, except as provided for by the strict procedures of this research study. Third, no identifiable report of participants' performance will be made to anyone.

Note that information about your participation in this research study (but not identifiable performance) may be shared with the Vanderbilt University Institutional Review Board and the Federal Government's Office for Human Research Protections (OHRP).

Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board, Federal Government Office for Human Research Protections, if you or someone else is in danger or if we are required to do so by law.

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STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate. You will be given copy of this form after it is signed.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title