Cover Page for ClinicalTrials.gov

Document:

Informed Consent Form

Official Study Title:

Improving Outcomes for Mechanically Ventilated Patients with the Digital EZ Board

Document Date:

July 24, 2018

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**VIDATALK™ COMMUNICATION APPLICATION: USABILITY, ACCEPTABILITY AND EFFICACY STUDY (Clinical Trial)**
Principal Investigator:	**Mary Beth Happ PhD, RN, FAAN**
Sponsor:	**National Institute of Nursing Research and Vidatak, LLC**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended effects that may be minor (such as fatigue) or more serious (such as information loss).
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The purpose of this research is to compare two electronic tablet applications for patients who are unable to speak while receiving treatment in the intensive care unit (ICU).

2. How many people will take part in this study?

A total of 70 patients in the critical care units will participate in this phase of the study, half will be randomly selected (liked flipping a coin) to receive demonstration of a common game application and half will receive demonstration of a new application.

3. What will happen if I take part in this study?

A member of the research team will find a good time to meet with you in your hospital room. The researcher will ask you some questions about your experience while in the intensive care unit and unable to speak. The researcher will then provide brief instruction and demonstration of the selected application. The tablet instruction session will be audio-recorded to assure quality. Members of the research team will visit you for 5-10 minutes each day while you have the tablet to ask about your use of the application and feelings, and check your thinking and level of sedation-relaxation, and satisfaction. We will ask you to recommend a family member or friend who visits you regularly in the hospital and may be willing to complete a brief satisfaction survey.

Some additional information from your medical record will be collected and include your name, primary diagnosis/procedure, the number of days that you received mechanical ventilation, medication use, hospital admission date, ICU admission date, age, sex, ethnicity, and acuity score. Your name will be kept separately from the rest of the information to protect your privacy and confidentiality

4. How long will I be in the study?

Our first session will take 30-40 minutes. If at any time you get tired, you may ask to stop and you can take a break and return to the study at a time that is convenient for you.

You will be in the study for the remainder of your stay in the intensive care unit. Members of the research team will visit you for 5-10 minutes each day before discharge from the ICU and while you have the tablet to ask about your use of the application, how you are feeling, how clearly you are thinking, and for ratings of communication difficulty. We will also get information from your medical record on medications, diagnosis, and clinical care.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your care or future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Fatigue (tiredness): If you are feeling too tired, or do not feel well enough to participate, or are unable to answer questions or to continue with the touch pad demonstration the researcher will stop the session.

The only risk associated with this study is an unintentional breech of confidentiality, but we make every effort to keep the information that you tell us, and any medical information that we may collect protected, private and secure. We use study identification numbers and your name will not be linked to the information that you provide in any research reports or publications, and all study information are contained in locked office and password protected computer files.

7. What benefits can I expect from being in the study?

There will be no direct benefits to you for participating in this study. You may or may not enjoy using the app. However, your participation may help patients who are unable to speak while on the breathing tube in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There will be no costs to you for participating in this study

10. Will I be paid for taking part in this study?

You will receive a $10 gift card for your participation. You will receive this even if you are unable to complete the study. By law, payments to subjects are considered taxable income.

11. What happens if I am injured because I took part in this study?

There is minimal to no risk of injury from participating in this study. However, if you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled, and there will be no change in your care in any way.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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

The NIH issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information, documents. The Certificates are issued so that we cannot be required to disclose any identifiable information collected about you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.
However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if the National Institute for Nursing Research that is funding this study requests the information, or if the FDA tells us to release this information.
Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Information from the medical records as detailed below;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;

- Information gathered for this research from surveys and questionnaires
- Medical Record Information including
  Demographics – age, race, sex,
  Diagnosis and condition
  Dates of hospital admission, discharge, breathing tube treatment and mechanical ventilation
  Physical restraint use
  Sedation medications;
- Records about the electronic tablet

II. Who may use and give out information about you

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;
- Others: National Institute of Nursing Research, Vidatak, LLC

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Mary Beth Happ at 614-292-8336.**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact: "HIPAA Privacy Officer, Suite E2140, 600 Ackerman Road, Columbus, OH 43201, Phone: 293-4477"

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Mary Beth Happ at 614-292-8336**

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I give permission to have the tablet instruction session recorded to monitor quality. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM**
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time