LITES Task Order 0005 Prehospital Airway Control Trial

(PACT) Consent for Continuing Participation

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University of Pittsburgh

CONSENT FOR CONTINUING PARTICIPATION IN RESEARCH

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STUDY TITLE: Prehospital Airway Control Trial (PACT)

SOURCES OF SUPPORT: This study is being funded by the Department of Defense (DoD)

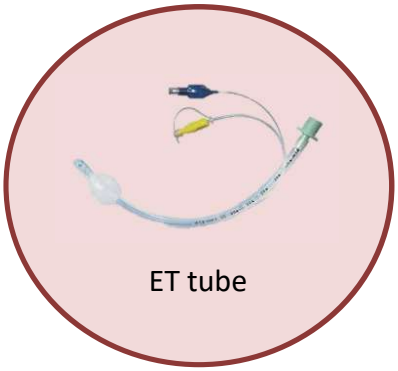
The word "YOU" throughout this document refers to the person injured. In cases where the injured person is unable to read and understand this form for themselves, this form is being provided to the legally authorized representatives acting on the injured person's behalf.

INTRODUCTION

You are receiving this notification and consent because you were enrolled in a research study, designed to compare different ways to help severely injured people breathe. This research study will enroll 2,009 patients across the country. The purpose of this form is to describe the study in which you are involved.

PURPOSE OF THE STUDY

This study is being done to compare different ways of helping people with traumatic injuries breathe. Currently, prehospital providers typically use one of two methods; one is with a tube in the windpipe, called an endotracheal (ET) tube, and the other is with a device that sits over the windpipe called a supraglottic airway (SGA). The ET tube is put through your mouth and into your windpipe, sending air into your lungs. The SGA devices sit over your windpipe and are put through your mouth and block air from going into your stomach, forcing air through your windpipe and to your lungs. Although both the ET tube and the SGA device are currently used by prehospital providers all the time, the SGA devices are not currently FDA approved for use in trauma patients.



To test these methods, we will ask some providers to use whatever method they would normally and some providers to try using the SGA first, and we will compare the two groups. Both methods are considered usual care.

Depending on what emergency service (EMS) transported you, you may or may not have been given one of the SGA devices. Due to your condition, the EMS providers would most likely have used either the ET tube or an SGA device to help you breathe anyway. All other medical care provided to you for your injury was standard care for your condition. Due to the nature of the emergency, it was impossible to obtain your informed consent before enrolling you in this study. This consent provides you with information so that you can decide if you want to continue in this study.

This study is only done in emergencies. The Institutional Review Board (IRB- committee that oversees research to protect subjects) has given permission to conduct this study without getting consent first. You may have already gotten an ET tube or an SGA device to help your breathing.

We would like to continue to collect information from your medical records to follow up on your health during your hospital stay and the treatment that you receive while in the hospital. The reason for getting this additional information is to better understand how the method used to help you breathe impacted your recovery. This information may include time spent with EMS and in the hospital and the type of care you got in the ambulance and hospital, information such as date of birth, age, gender, vital signs, lab test results, medications, medical procedures, and any illnesses or set-backs you experience while you are in the hospital. We will collect information about how each of your body systems is doing by recording lab values and procedures that are done as part of your care. We will collect information from your record throughout your hospitalization until you are discharged.

Your data may be shared with other scientists and researchers outside of UPMC/University of Pittsburgh. Your name and identifying information will be removed from the data and will be replaced with a unique code before they are sent to anyone.

Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

POTENTIAL RISKS AND DISCOMFORTS
There are risks as part of being in this study. Please note that you have already been exposed to some of these risks, but due to the seriousness of your injury, these procedures would have been performed on you anyway as part of your medical care.

Regardless of what ambulance you were in, EMS helped you breathe with a mask, an ET tube, or an SGA device. Some EMS providers were told ahead of time to use the SGA first to help you breathe. In this case, if after the first try the SGA didn't work, the EMS provider was allowed to use whatever method s/he wanted to use to quickly help you breathe.

The risks of emergency airway management include vomiting, low oxygen levels, mouth injury, esophagus injury, breathing tube injury, lung injury, brain injury, gastrointestinal injury, collapsed lung (pneumothorax), lung inflammation (pneumonitis), acute respiratory distress syndrome (ARDS), ventilator associated pneumonia (VAP), and death. These risks occurred regardless of you being part of the study. The risks of being enrolled in this study are related to telling the EMS provider which method to use first. We don't know if telling the provider which method to use first makes the risks above better or worse. There may also be other risks to participating in the study that we don't know yet.

The only risk of continuing participation in this study is a risk to confidentiality, which is discussed in a paragraph below.

ANTICIPATED BENEFITS TO SUBJECTS
We are conducting this study to compare methods of helping injured patients breathe and are unsure if there are any benefits to one method over another. You may be at a lower risk of delayed breathing support, which can cause low blood pressure, not enough oxygen in your blood (hypoxia), and death. Also, you may have benefited from the additional training on trauma airway management that all EMS providers participating in the study have received. Your participation may help us to improve future pre-hospital treatment of trauma injuries.

COSTS OF PARTICIPATION
There are no additional costs to you for continuing to participate in this study. Clinical care provided, including placement of the ET tube or SGA device, will be charged in the usual manner as part of your standard medical care (care you would receive even if you were not participating in this research study).

MEDICAL CARE FOR RESEARCH RELATED INJURY
UPMC and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise because of this research. If you believe that you are injured because of the research procedure being performed, please immediately contact the principal investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that the hospital may bill your insurance provider for the costs of this emergency treatment but none of these costs will be charged directly to you. If your research related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated above. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

CONFIDENTIALITY
We make every effort to keep the information about you confidential. You have been given a study code number. This code number, and not your name, is used on all the data we collect. The data collected may be shared with other doctors and research scientists outside of the University of Pittsburgh/UPMC. A key linking you to the code number is kept in a secure location and will be available only to the investigators and their research teams. The data will be retained indefinitely and used for future studies. Data from this study, without your identity, may be reported in scientific meetings, articles or other appropriate communications. We will notify the community of the results through scientific papers, presentations at scientific meetings, and through local media.

If you sign this document, you give permission for continued access to your health information that identifies you for the research study to the following groups: the investigators listed on the first page of this consent form and their research staff, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office, the Department of Defense, and the FDA. This information can be requested by and provided to courts or legal authorities. Authorized representatives of the University of Pittsburgh/UPMC or other affiliated health care providers may have access to your identifiable information (which may include your identifiable medical record information) for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (such as laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).

SUBJECT ACCESS TO RESEARCH RESULTS
In accordance with the University of Pittsburgh/UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to research results contained within your medical records filed with your health care provider. Please note that such access may be limited to the end of the research study.

A description of this clinical trial will be available on *http://www.clinicaltrials.gov*, as required by US 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 this website at any time.

PARTICIPATION AND WITHDRAWAL
Your continued participation in this research is voluntary. If you choose not to continue to participate, that will not affect your relationship with your providers or your right to health care or other services to which you are otherwise entitled. If you decide to continue to participate, you are free to withdraw your consent and discontinue further participation at any time without prejudice.

CONSEQUENCES OF WITHDRAWAL
If you chose not to continue to participate, we will not collect any additional information from your medical record. However, any data already collected will be retained.

NEW FINDINGS
During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation. If new information is provided to you, we will ask for your consent to continue participating in this study again.

IDENTIFICATION OF INVESTIGATORS
In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact the PI or Co-PI listed on the first page of this form.

RIGHTS OF RESEARCH SUBJECTS
You may withdraw your continuing consent at any time and discontinue further participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Human Subjects Protection Advocate toll-free at 866-212-2668.

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RESEARCH SUBJECT CONSENT
(complete when initial consent is obtained from the subject)

VOLUNTARY CONSENT
The study has been described to me and all of my questions have been answered. Any additional questions or concerns about any aspect of this study will be answered by the researchers. Questions I might have about my rights as a research participant will be answered by the Human Subject Protection Advocate at toll-free at 866-212-2668.

By signing this form, I agree to continue to participate in this research study. A copy of this consent form will be given to me.

_____	_____	_____	_____
Participant's Signature	Printed Name of Participant	Date	Time

SURROGATE CONSENT
(complete when subject is unable to consent for themself)

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_____ is unable to provide direct consent for study participation.
Participant's Name (Print)

Therefore, by signing this form, I give my consent for his/her continued participation in this research study.

_____	_____
Representative's Name (Print)	Relationship to Participant

_____	_____	_____
Representative's Signature	Date	Time

CONSENTER'S CERTIFICATION
(for initial subject or surrogate consent)

I certify that the nature and purpose and the potential benefits and possible risks associated with participation in this research study have been explained to the subject or his/her family member and any questions about this information have been answered.

_____	_____
Name of Person Conducting Informed Consent Discussion (Print)	Role in Research Study

_____	_____	_____
Signature of Person Conducting Informed Consent Discussion	Date	Time

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CONSENT FOR CONTINUED RESEARCH PARTICIPATION
(complete only if consent was obtained from surrogate and subject has regained ability to consent)

I am currently participating in a research study in which consent for my participation was initially obtained from my legally authorized representative as a result of my inability to provide consent at the time. I have now recovered to the point where the study doctor believes that I am able to consent to continued participation in this research study.

I have read the information in this consent form. The study has been explained to me, and all of my current questions have been answered.

I agree to continue my participation in this research study.

_____
Participant name (print)

_____ _____ _____
Participant Signature Date Time

CONSENTER'S CERTIFICATION
(for continued research participation)

I certify that the nature and purpose and the potential benefits and possible risks associated with participation in this research study have been explained to the subject and any questions about this information have been answered.

_____ _____
Name of Person Conducting Informed Consent Discussion (Print) Role in Research Study

_____ _____ _____
Signature of Person Conducting Informed Consent Discussion Date Time