Vacuum vs Manual Drainage During Unilateral Thoracentesis

Informed Consent Form

NCT 03496987

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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Title: **Thoracentesis using Manual Aspiration vs Vacuum Suction: A Study Comparing Pain and Complications**
Principal Investigator: Jonathan Puchalski, MD
Study Sponsors: Pulmonary, Critical Care and Sleep Medicine Section, Yale University School of Medicine

(For patients)

Invitation to Participate and Description of Project:

You are invited to participate in a research study designed to learn more about thoracic procedures. You were chosen to be part of our study because you are having fluid drained from your chest that has accumulated in pleural space (pleural effusion). Drainage of the fluid is a standard, commonly performed procedure called thoracentesis. The procedure is performed to determine why there is a pleural effusion and to relieve symptoms caused by this fluid. This study will enroll approximately 100 patients from Yale-New Haven hospital.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This form gives you detailed information about the research study and a member of the research team will discuss this with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of participating in the research and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

This research collects data to determine which way of draining fluid is best for patients. The best way is not currently known but the two methods including removing the fluid using a syringe pump and removing the fluid with a vacuum bottle. We want to determine which technique has less pain and less complications. You will have the thoracentesis regardless of whether you participate in the study.

Description of Procedures:

If you agree to participate in this study, we will ask you to complete Numeric Pain Rating Scale where you determine your pain prior the procedure and during the procedure. We would also like to review your hospital record for information about your thoracic procedure such as reasons for the procedure, site of procedure performed, and results of procedure.

The procedure, which is not part of the research, will be performed using a standard thoracentesis kit. Once is the catheter is in place, the fluid will be drained by either manual

evacuation or using a vacuum container. At present, there is not enough information to determine if one form of drainage is better than another.

Risks and Inconveniences:

This study presents minimal risks to you. The pain assessment will take only a few minutes of your time to complete. All information regarding procedures will be abstracted from the medical chart by trained research staff. The fluid collected during procedure will undergo standard analysis to best determine the reason for its accumulation. There are no additional tests, procedures or imaging that you will have to undergo just because you decide to participate in the study.

Benefits:

This study is not designed to benefit you directly. Study participation will help us better understand procedures and outcomes. It may help us find ways to improve care.

Economic Considerations:

There will be no payment for participation. There are no costs associated with this study. Your fluid will be used only for standard testing. However, the research done with your participation may help to develop new products in the future. You will not receive any payment if this happens.

Alternatives:

Participation in this study is strictly voluntary. The only alternative is to not participate in this study. If you decide to do so you will be offered thoracentesis anyway, but without collecting additional data about your pain.

Confidentiality and Privacy:

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases.

Your research records will be kept as confidential as possible. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.) The master list linking names to code numbers will be kept separately from the research data. All research information will be kept in locked files at all times. All research data is stored on password-protected computers and servers. Only authorized persons will have access to the information gathered in this study.

Once your participation in the study is finished, it will not be possible for you to withdraw the information we have collected.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, gender, age and medical conditions. This information will be kept until only until data are entered into a database. After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to other members of the research team to carry out this research study.

The information about your health that will be collected in this study includes:

- *Research study records*
- *The entire research record and any medical records held by Yale created from: 12/1/2015 to: 06/30/2016.*
- *The following information: name, age, gender, and past medical history.*

Information about you and your health which might identify you may be used by or given to:

- *Representatives from Yale University and the Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for insuring research compliance. These individuals are required to keep all information confidential.*
- *The Principal Investigator Jonathan Puchalski*
- *Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.*
- *Co-Investigators and other investigators*
- *Study Coordinator and Members of the Research Team*

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff atYale School of Medicine and Yale-New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may

not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. 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.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

Voluntary Participation:

Participation in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for the your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Questions:

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Withdrawing From the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. 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.

The researchers may withdraw you from participating in the research if necessary.

Withdrawing Your Authorization to Use and Disclose Your Health Information:

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Jonathan Puchalski 15 York St LCI 100 New Haven, CT 06510.

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 until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Authorization:

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. By signing the consent form to participate in this research study I am not giving up any of my legal rights. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Principal Investigator Date
or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Dr. Jonathan Puchalski can be reached at 737-4208*. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688.*