Pleural Manometry for the Characterization of Spontaneous and Tension Pneumothorax

NCT04630301

7/6/2021

WAIVER OF DOCUMENTATION OF CONSENT SCRIPT

Protocol Title: Pleural Manometry for the Evaluation of Spontaneous and Tension Pneumothorax

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KEY INFORMATION

The condition of having air in the chest cavity is called a pneumothorax. This condition is treated by placing a chest tube to drain the air. The purpose of this study is to measure the pressure of the air in the chest cavity. While the chest tube is being placed, the pressure of the air will be measured. The condition of participants will then be monitored by reviewing medical records.

The risk of participation is that personal information may become known to people outside of this study. There is no benefit to or costs associated with participating in this study. This research study may help treatment of patients in the future.

PURPOSE

You are being asked to take part in this research study because you had a pneumothorax that required a chest tube. The purpose of this study is to measure the pressure of the air in your chest cavity.

PROCEDURES

While your chest tube was inserted, the pressure of air inside your chest was measured. This measurement is being stored in a secured and encrypted database. We are now asking your permission to use that measurement in our study and to monitor the status of your pneumothorax by reviewing your medical records. This measurement and information from your medical records will be recorded in the same database. If you decide not to join this study, the measurement information will be discarded and your medical record information will not be collected.

RISKS/DISCOMFORTS

Involvement in this study does not pose any increased risk or cause increased discomfort for you. You have undergone standard chest tube placement to drain the air surrounding your lung, and the pressure of this air was measured.

Identifiable private information

There is the risk that information about you may become known to people outside this study. To minimize this risk, your information will be stored on a secure and encrypted database that can only be accessed by the study team members. Once all needed data are collected, any identifiable information will be deleted from the database.

BENEFITS

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

VOLUNTARY PARTICIPATION

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your care at Johns Hopkins. You can agree to be in this study now and change your mind later. If you wish to stop, please tell us right away and all stored information related to you will be deleted from the database. Leaving this study will not stop you from getting regular medical care.

IDENTIFIABLE INFORMATION IN FUTURE RESEARCH

We may use the information collected through this study for future research including research with external collaborators. All information that could identify you (like your name or medical record number) will be removed before any data is shared.

HIPAA DISCLOSURE

We will collect information about you in this study. People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly will see the information.

People at Johns Hopkins may need to send your information to people outside of Johns Hopkins (for example, government groups like the Food and Drug Administration) who need to make sure the study is being done correctly. These people will use your information for the purpose of the study.

Your Authorization for the collection, use, and sharing of your information does not expire. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and do not want your information to be used for the study, you must contact the Principal Investigator by using the contact information provided in this document. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but, we cannot guarantee this.

CONTACT INFORMATION:

If you have any questions about this study, please feel free to contact the Principal Investigator Dr. Jeffrey Thiboutot at 410-502-2533 or jthibou1@jhmi.edu.

The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.