MAYO CLINIC

Name and Clinic Number

Approval Date: **September 13, 2019**
Not to be used after: **April 4, 2020**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: A Randomized Study Evaluating Patients Discharged with Indwelling Chest Tube and Valve

IRB#: 17-007774

Principal Investigator: Dr. K. Robert Shen and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.

It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to gather information about the effectiveness of antibiotics and closer monitoring on decreasing infections and hospital readmissions when patients discharge from the hospital with a chest tube and valve in place. You have been asked to take to take part in this research because you are being discharged from the hospital with a chest tube and valve in place.
What's Involved	Study participation involves being randomly put into one of two groups to either receive antibiotics and twice weekly phone calls or usual care following discharge from the hospital. You will be in the study for 30 days following discharge from the hospital or until the chest tube has been removed if it remains in place more than 30 days post hospital discharge.

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Key Information	All study interventions could be considered standard of care. Receiving oral antibiotics may increase the risk of drug resistance and secondary infections. Not receiving antibiotics may increase your risk for infection of the fluid in the chest. This study is only being done to gather information. You may choose not to take part in this study. Others discharging from the hospital with a chest tube in place may benefit in the future from what we learn in this research study.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator(s):** K. Robert Shen, M.D. **Phone:** (507) 266-0911 **Study Team Contact:** Thoracic Surgery Clinical Research Unit **Phone:** (877) 526-9172 **Institution Name and Address:** Mayo Clinic Rochester (877) 526-9172
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

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Other Information:
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 this Website at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you will be discharged from the hospital with a chest tube and valve in place.

About 560 people will take part in this research study.

Why is this research study being done?

The purpose of this study is to gather information about the effectiveness of antibiotics and closer monitoring on decreasing infections and hospital readmissions when patients discharge from the hospital with a chest tube and valve in place.

Information you should know

Who is Funding the Study?

The study is being funded by the Mayo Clinic Division of General Thoracic Surgery.

How long will you be in this research study?

You will be in the study for 30 days following discharge from the hospital or until the chest tube has been removed if it remains in place more than 30 days post hospital discharge.

What will happen to you while you are in this research study?

If you decide that you would like to participate in this study, you will be asked to sign this consent form. You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. Neither you nor your study doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

- **Group 1:** Will receive oral antibiotics to take while the chest tube is in place and twice weekly phone calls.
- **Group 2:** Will receive the care you would receive if you were not on the study.

Visit 1

The study coordinator will meet with you to sign the consent form and randomize you into one of the two groups. For women of childbearing potential, a pregnancy test will be done if not done prior to surgery and it must be negative before you can continue in this study. Baseline data collected which includes air leak status and surgical history.

Visit 2

Prior to their discharge from the hospital a member of the study team will review the instructions for completing the Patient Chest Tube Diary and will confirm that the standard clinical education for discharging with an indwelling chest tube and valve has been completed.

Daily Diary

You are asked to complete the Patient Chest Tube Diary daily until the chest tube is removed.

- Group 1-This includes information about the air leak and how it has changed and if you took your antibiotic.
- Group 2- This includes information about the air leak and how it has changed.

The daily diary will be returned at your follow up visit to have your chest tube removed or you will receive an envelope to mail it back to the research team.

Or you may opt to use the Medidata Patient Cloud App to enter your daily diary information. If you choose to use the app, we will ask you for your email address which we use to send you the invitation to the application.

Twice Weekly Telephone Calls (Group 1 Only)

The subjects in Group 1 will receive twice a week telephone calls from their coordinating medical team until the chest tube has been removed.

What are the possible risks or discomforts from being in this research study?

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

All study interventions could be considered standard of care. Receiving oral antibiotics has risks.

Group 1 (Oral antibiotics and twice weekly phone calls):
The most common side effects of the antibiotics include:

- Diarrhea
- Dizziness
- Tiredness
- Headache
- Stomach upset
- Abdominal pain
- Joint pain
- Vaginal itching or discharge
- Nausea
- Vomiting
- Itching
- Swelling
- Rash
- Heart burn
- Sore throat
- Changes in bowel habits

More serious and less common side effects include:

- Severe stomach pain, diarrhea that is watery or bloody
- Jaundice (yellowing of the skin or eyes)
- Easy bruising, unusual bleeding (nose, mouth, vagina, or rectum), purple or red pinpoint spots under your skin
- Little or no urination, dark urine

- Agitation, confusion, hallucinations
- Severe skin reaction--fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.

Group 2 (Care you would receive if you were not on the study):

- Empyema or infection of the fluid in the chest which can lead to readmission to the hospital, antibiotics, additional drain placement or reoperation

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest
- If you don't follow the study procedures
- If the study is stopped

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

Others discharging from the hospital with a chest tube in place may benefit in the future from what we learn in this research study.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- *Twice weekly telephone calls (Group 1)*
- *Pregnancy test, if needed*

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- *Antibiotics (Group 1)*

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

All electronic data will be kept within the secure database and Mayo Clinic firewall and will only be accessed by study team members. Information that is printed will be kept in a locked cabinet only accessed by study team members.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

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

- To do the research.
- To report the results.
- To see if the research was done correctly.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media) information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

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Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.
Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

CSig

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature