MAYO CLINIC

Name and Clinic Number

Approval Date: **April 24, 2024**
Not to be used after: **April 23, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: A study to evaluate the efficacy of pleural space saline irrigation in addition to standard intrapleural thrombolytic therapy in the management of empyema/complicated parapneumonic effusion

IRB#: 23-013234

Principal Investigator: Dr. Dagny Anderson 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 see if there is any benefit in adding doses of normal saline through a chest tube to the standard course of treatment for diagnosed or suspected bacterial infection in the pleural space. You have been asked to take part in this research because you have a diagnosed or suspected bacterial infection in the pleural space.
What's Involved	Participating in this study will last 3 months or less, depending on your response to treatment. During the study, you will be randomly assigned to one of two groups. One group will receive standard treatment for bacterial infections in the pleural space, the other will receive standard treatment and saline.

	If you are assigned to the group receiving saline, you will receive daily doses of normal saline through your chest tube after receiving your standard treatment. At the end of treatment, both groups will fill out a survey regarding how well treatment was tolerated We will also review your medical record for information relating to your infection throughout the study to help monitor your infection and to determine when you no longer need treatment.
Key Information	Risks of normal saline may include fever, respiratory failure, and infection. We cannot promise that you will receive any benefits while you are in this study, but it may reduce the need for surgery. You will not be paid for your participation.
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.

If you are signing this consent form for someone else, "you" in the consent form refers to the participant.

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):** Dr. Dagny Anderson **Phone:** (507) 284-3104 **Study Team Contact:** Study Coordinator **Phone:** (800) 753-1606 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ 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 Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

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 have a bacterial infection in the fluid between your lungs and the wall of your chest cavity (pleural space).

The plan is to have about 60 people take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this study is to see if there is any benefit in adding doses of normal saline through a chest tube to the standard course of treatment for people diagnosed or suspected of having a bacterial infection in the pleural space (the space between the lungs and the wall of the lung cavity).

Information you should know

Who is Funding the Study?
The United States Department of Defense is funding this study. The Department of Defense will pay the institution to cover costs relating to running the study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in this study for 3 months or less depending on your response to your treatment.

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

This study will have two groups, those who will receive standard of care treatment for bacterial infections in the pleural space (control group) and those who will receive normal saline in addition to standard treatment (intervention group). You will be assigned to your group by chance. You and the study doctor will not be able to choose your study group, but you will

know to which group you were assigned. You will have an equal chance of being assigned to either group. The procedures for each visit are described below.

Visit 1 (Baseline)

- You will sign and date this consent form.
- You may be asked questions about you, your medical history, and your current medications.
- You will receive your dose of standard treatment.
    - If you are assigned to the intervention group, you will receive your first dose of normal saline through your chest tube after your standard treatment.

Treatment Period

During the study, you will receive daily doses of standard treatment or standard treatment and saline through your chest tube each morning until your doctor decides that you no longer require standard treatment. As needed clinically, you may have daily chest x-rays and ultrasounds. These will not be part of the study, but the results will recorded for the study and will also be used to monitor your infection and help determine when to stop your treatment.

Final Visit

The treatment portion of the study will be complete once it has been determined that you no longer need standard treatment. At this time, you will be asked to complete a survey asking you questions about how well you think you tolerated your treatment.

Medical Record Review

During the study we will be reviewing your medical record and recording information needed for the study. Information that we will use may include:

- Information about your infection
- Clinical assessments and physical exams
- Changes in medications and additional procedures
- Blood test results
- Pleural fluid test results
- Chest x-rays
- Ultrasounds
- Pregnancy tests (women of childbearing potential)
- Any medical events since the start of the study

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

Risks associated with receiving normal saline may include fever, respiratory failure, and infection.

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

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?

This study may not make your health better. However, participating in this study may reduce your need for surgery due to complications from your bacterial infection.

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

You don't have to be in this study to receive treatment for your condition. You may choose to only receive standard treatment for your bacterial infection. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

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:

- Questionnaire
- Normal Saline

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:

- Standard treatment
- Chest X-rays and ultrasounds
- Pregnancy test (women of childbearing potential)
- Blood tests
- Pleural fluid tests

You and/or your insurance may also have to pay for other drugs or treatment given to control side effects. 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?

Your information collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

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.

Data collected for this study will be deidentified and a secure database will be used to store the information. Access to this database is limited. Only people who are involved with the study will have access to information collected for this study.

Authorization to Use and Disclose Protected Health Information (HIPAA)
During this research, information about your health will be collected. Under Federal law called the Privacy Rule (also referred to as Health Insurance Portability and Accountability Act [HIPAA]), 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.

Your health information may be collected from:

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

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Other healthcare providers involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- Department of Defense representatives.
- The Mayo Clinic Institutional Review Board that oversees the research.
- 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.

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 <u>not</u> 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.

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
200 First St. SW
Plummer Building PL 3-02
Rochester, MN 55905
Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@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.

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

Signature of Legally Authorized Representative for Adult Participant

- I give permission for the participant to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Signature Printed Name Relationship to Participant Date \ Time

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.

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

Signature