MAYO CLINIC

Name and Clinic Number

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

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Efficacy of self-management of sedative therapy by ventilated ICU patients

IRB#: 16-000417

Principal Investigator: Linda L. Chlan, Ph.D. and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

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.

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 a copy of this form to keep. A copy of this form will be put in your medical record.

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

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. Linda L. Chlan **Other Study Team Contact:** \ Nursing Research Division – Study Coordinators	**Phone:** (507) 255-7859 **Phone:** (507) 422-5523 **Institution Name and Address:** Mayo Clinic Hospital Saint Marys Campus 1216 2nd St SW Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Participant Advocate **(The RPA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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1. 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 are hospitalized in an intensive care unit (ICU), receiving mechanical ventilation (respirator, breathing tube) and your physician is not planning on extubating (removing the breathing tube) you imminently.

The plan is to have up to 120 people take part in this study at Mayo Clinic Rochester.

2. Why is this research study being done?

The purpose of this study is to compare two ways of receiving medicine to keep you comfortable while you have the breathing tube in place. These two methods are either nurse-administered or patient self-administered.

3. Information you should know

Who is Funding the Study?
This study is funded by the National Heart, Lung & Blood Institute (NHLBI), National Institutes of Health (NIH). The NIH will pay Mayo Clinic to cover the costs related to conducting the study.

Information Regarding Conflict of Interest:
The Mayo Clinic Conflict of Interest Review Board will oversee any conflict issues, should they arise, within the relationship between Mayo Clinic and the NHLBI.

4. How long will you be in this research study?

You will be in the study for six months from the time you are discharged from the ICU.

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

For Female Patients Only: You must not be pregnant to participate in this study. If you are female and under 50 years of age, to make sure you are not pregnant, we will first do a pregnancy test (urine or blood). You will be eligible to participate in this study if the pregnancy test is negative.

All Patients
If you are eligible and agree to participate in this study, we will assign you by chance (like a coin toss) to one of two groups (below) to manage feelings of anxiety and relaxation with an FDA-approved sedative drug called dexmedetomidine [deks″med-ĕ-to´mĭ-dēn]. Dexmedetomidine (DEX) is also known as Precedex ® and Dexdor ® and is commonly used and routinely administered to ICU patients receiving mechanical ventilation. You and the Principal Investigator cannot choose your study group. You will have a 50/50 chance of being assigned to either group:

1) Self-Management of Sedative Therapy (SMST) Group, or
2) Usual Care Group

If you are assigned to the **SMST Group:**

- You will self-manage your dexmedetomidine dosing schedule within the study guidelines as developed by the research team. This is in addition to a continuous infusion of dexmedetomidine into your vein.
- If you feel anxious and/or desire to receive medication for relaxation, you will have the choice to press a push-button device to give yourself a dose of the dexmedetomidine medication. You can also receive supplemental sedative medications if, in the judgment of the patient-care ICU nurse, these are needed for these symptoms.
- In addition to the attentive and careful monitoring of ICU standards of nursing care, assessment visits from research staff will occur every 8 hours to ask you questions about your anxiety, and assess your alertness and your mental state, and will also include a review of the push-button device operation.
- You will continue to self-manage your sedative medication for up to 7 days on this study plan, unless there is reason for leaving the study early, as described in Section 7 of this form. If you remain on the mechanical ventilator after 7 days, the sedative plan will be ordered by your physician.
- At the end of this 7-day study, the research staff will ask you three questions about your level of satisfaction with the self-administration of medication.

If you are assigned to the **Usual Care Group:**

- You will continue on your current sedative medication plan, which could also include the drug dexmedetomidine, with doses of medications ordered by your primary medical care team and given by the patient-care nurse per standard ICU practice guidelines. These standard sedative management plans consist of bedside patient-care ICU nurses managing the physician-prescribed sedative medications based on your arousal and alertness.
- The research staff will also ask you about your anxiety, and assess your alertness and mental state every 8 hours. Your nurse will follow this study plan for up to 7 days, unless there are reasons for leaving the study early as described in Section 7 of this form.

Both Study Groups:

- The study team will collect demographical information from your medical record, things like age, gender, race, medical diagnoses, and other medical information related to being on a ventilator in the ICU.
- Approximately 24-48 hours after the breathing tube has been removed, and after you leave the ICU and are home, a member of the research team will call you on the telephone at 3 and 6 months to ask you questions about your physical and functional health, psychological well-being, and your quality of life. We estimate the phone calls will take approximately 45 minutes each.

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

There may be additional potential risks associated with participation for those assigned to the SMST group, as described in the first three paragraphs below:

You may not feel relaxed after giving yourself the medication. This risk is thought to be minimal and the nurse can increase the amount of study medication (dexmedetomidine) or administer additional medication at any time, if the nurse thinks it is necessary for your well-being.

You may become less alert after giving yourself the dexmedetomidine medication. Decreasing alertness is a known effect of the medication; if you become less alert, less medication will be delivered. The risk of excessive sedation is low and its consequences are minor since the ventilator will support breathing.

Your heart rate and blood pressure may be lower for a short time. This risk is thought to be low as those patients who are more at risk for developing lower heart rates and blood pressures are not participating in this study. You will be closely monitored and the study medication will be discontinued if necessary. The ICU physicians overseeing your care may remove you from the study if they feel your heart rate, blood pressure, or medical conditions changes such that continuing in the study would cause you harm.

For all participants:
There is a risk to maintaining confidentiality of any study participant. This risk is thought to be low because we will keep all data collection forms in a locked file cabinet, and all electronic data will be stored in a password protected database with access limited to only the necessary research team members.

You may feel an invasion of your privacy when approached for study participation by a member of the research team, and/or when a member of the study team visits with you three times each day to ask you about your anxiety, alertness and mental state.

You may feel burdened by responding to questions about your anxiety, alertness and mental state three times a day while on the study for up to 7 days. This risk is thought to be low given that our experienced study personnel will ask you these questions in a gentle, un-hurried manner.

There is risk for invasion of privacy when being contacted twice in a 6-month time frame for the follow-up phone calls after you are at home. This risk is thought to be low as you will be asked to complete the questionnaires over the telephone in the convenience of your home at a time that is convenient for you.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator or a member of the research team if you decide to stop.

In addition, the Principal Investigator at 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
- for safety reasons
- if the study is stopped

If you stop this research study early, or are removed 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.

8. 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 on page 2 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 company. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

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

This study may not make your health better, and there may be no benefits to participation in this study. If you are assigned to the SMST group, you may feel more in control as a result of administering a relaxing medication to yourself and you will not have to ask the nurse for medication. Other ICU patients may benefit in the future from what we learn in this research study.

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

Patients who choose not to participate in this study will continue to receive the standard ICU care on the unit which consists of sedative medications administered by and at the discretion of the bed side ICU nurses with medications selected and ordered by the ICU physician.

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

There are no research-related charges or procedures for taking part in this research study that you will need to pay.

The medication (dexmedetomidine) used in this study and the pregnancy test for females under age 50 are being paid for by the National Institutes of Health.

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, including 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.

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

You will not be paid for taking part in this study.

13. 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 obtained study data will be kept electronically in password protected data files. Paper files will be kept in a locked file cabinet in the Principal Investigator's research offices with use restricted to the research staff only. Data for each subject will be stored in a lettered and numbered folder. The only personally identifiable records for this study will be the signed consent forms, a home telephone number log, and a health survey (SF-36) that is electronically scored. They will be stored in a locked file cabinet, separate from other study documents. Members of the research team, Data and Safety Monitoring Board, monitors from the University of Minnesota, the FDA, and NIH will have access to these signed documents and data files if requested during monitoring visits or audit inspections.

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.

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Health information may be collected about you from:

- Past, present and future medical records.
- Research monitoring procedures, including research assessment visits and questionnaires.

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.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.
- University of Minnesota Medical Center (UMMC) research staff.
- National Heart, Lung & Blood Institute (NHLBI), NIH.
- Food and Drug Administration.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians and researchers involved in your clinical care.
- Federal agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the NHLBI, NIH).
- University of Minnesota Clinical and Translational Sciences Institute Regulatory Monitoring office, the group that will oversee the medication safety of this research.
- The Data and Safety Monitoring Board, the group that oversees the study information and safety of this research.

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, 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 Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission 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.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors at Mayo Clinic or UMMC.

You can cancel your permission 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 1st Street SW
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 lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

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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

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