CAMC Health Education and Research Institute, Inc. (CHERI)
Charleston, West Virginia

OUTCOMES RESEARCH
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

PLACE PATIENT IDENTIFICATION LABEL HERE

DATE:

Patient Name:	APPROVAL

CAMC Health Education and Research Institute, Inc.
Center for Health Services and Outcomes Research
3200 MacCorkle Avenue, S.E.
Charleston, WV 25304

RESEARCH INFORMATION AND CONSENT FORM

Study Title: Prospective single-blinded randomized study of ketamine/midazolam sedation vs. fentanyl/midazolam sedation for image-guided percutaneous procedures in interventional radiology

Study Protocol No.: 24-1149

Sponsor: Maier Foundation

Investigator: Amy Deipolyi, MD, PhD, FSIR, Michael Korona, MD, Frank H Annie, PhD, Adam M Belcher, PhD, Elaine D. Mattox, RN, EdD

Phone #: **304-388-9920**

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Key Information

Introduction
This form gives you important information to help you decide if you want to take part in a research study. The doctor or staff doing the research can answer any questions you have. Make sure to read everything below and ask questions if you don't understand something. If you decide to join the study, you will sign this form to show you agree. You must be at least 18 years old to take part.

Why am I being asked to take part in this research study?
You are being asked to join a study about sedation (medication to make you relax or sleep) used during certain medical procedures. The study will compare two common ways of giving sedation: one with fentanyl and midazolam, and another with ketamine and midazolam. This study will include about 250 patients. Taking part is completely up to you. You can say no or stop at any time without any problems or affecting your medical care at Charleston Area Medical Center (CAMC).

Do you have to participate?
No, you don't have to take part in this study. You can choose not to join, or you can stop at any time. If you decide to stop, it won't cause any problems for you, and your care at CAMC will continue as usual.

Instructions for Participation:
If you decide to take part, follow these steps:

1. Read this form carefully.
2. Ask any questions or let the research team know if you have any concerns.
3. If you agree to join, sign the form at the bottom.
4. Give the signed form to the research team.
5. You will get a copy of this signed form to keep for your records.

Purpose of the Study
You've been asked to join a study to help improve sedation (medication for relaxation or sleep) during certain medical procedures. These are either a bone biopsy, a lung biopsy, or a drainage procedure. The goal is to find out if sedation with fentanyl and midazolam, or sedation with ketamine and midazolam, works better to make patients comfortable and reduce pain during and after the procedure. The study will also check if one method is safer than the other by looking at any problems caused by the procedure or sedation. You will be asked to rate your pain before, during, and after the procedure, and fill out a short questionnaire about your experience with the sedation. A study coordinator will help you fill out the questionnaire, which should take less than ten minutes.

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How long will it take?
The study will happen on the same day as your procedure and will add no more than 10 extra minutes to your recovery time. The surveys you need to fill out will take less than 10 minutes.

Time Point	Activity
First Visit	• Sign up for the study • Give permission to participate • Rate your pain on a 10-point scale before, during, and after the procedure • Fill out a short 10-minute survey about your experience with sedation
During the Study	• Doctors will collect health data as part of your regular care. No extra tests or time are needed.

What Will You Be Asked to Do?
If you join this study, you will randomly receive either ketamine or fentanyl for sedation during your procedure. This is a single-blinded study, meaning your doctor will know which medicine you get, but you will not. You will need to sign a form saying you understand that your medical information will be used for research. This includes your basic information, medical history, test results, and details about your procedure and sedation. Your participation is completely voluntary, and you can stop at any time. The research team is available to answer your questions and help as needed.

What Are the Risks?
The risks of joining this study are low. Your personal medical information will be kept private and protected. All study data will be stored securely and de-identified after the study.

The sedation medications used in this study are already commonly used for procedures. You will not need any extra tests beyond what is normally done. Both types of sedation are approved for use by the FDA and are used regularly by your doctor for your procedure. Your doctor will talk to you about the risks of sedation as part of your standard treatment and can answer your questions. Below are the known risks of fentanyl/midazolam and ketamine/midazolam sedation.

Fentanyl/midazolam:

- Nausea/vomiting: 10-20%
- Dizziness: 10-20%
- Difficulty breathing: <10%
- Low blood pressure: <10%
- Low heart rate: <10%
- The medicine makes you more, not less awake: <1%
- Your muscles become rigid: <1%
- Allergic reactions: <1%

Ketamine/midazolam:

- Nausea/vomiting: 10-20%
- Dizziness: 10-20%
- Temporary hallucinations/confusion: 10-20%
- Difficulty breathing: <10%
- Low blood pressure: <10%
- Low heart rate: <10%
- Severe high blood pressure: <1%
- The medicine makes you more, not less awake: <1%
- Your muscles become rigid: <1%
- Allergic reactions: <1%

If you choose not to join, you can still receive sedation and have your procedure as planned.

What Are the Benefits?
This study may not directly benefit you. However, it could help future patients if one sedation method is found to be better than the other.

Can I Choose Not to Participate?
Yes. You can still have your procedure with or without sedation, even if you don't join the study. You and your doctor will discuss which sedation to use.

Will This Cost Me Anything?
Any medical tests or procedures needed for the study are part of routine care, so they will not be paid for by the research team. You or your insurance will have to cover these costs, including co-pays and deductibles.

What Happens If I Am Hurt During the Study?
If you have a medical issue because of the study, you can receive emergency treatment at CAMC. However, joining the study does not guarantee that you will get financial compensation for any costs related to side effects.

For more information about risks or injuries, you can contact your study doctor at CAMC Interventional Radiology (304-388-0193) or Dr. Belcher at the CAMC Health Education and Research Institute (304-388-9920).

Will I Have to Pay for Travel or Childcare?
Yes. The study will not pay for travel, hotel stays, childcare, meals, or any other costs.

Will I Be Paid for Joining the Study?
No. You will not be paid for participating.

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How Will My Information Be Protected?
We will do everything we can to keep your information private, but we cannot guarantee complete confidentiality. Your records may be seen by the research team, CAMC staff, government agencies (like the FDA), and other groups that oversee research.

If results from this study are published or presented, your name will not be used.

Who Can I Contact About My Rights?
If you have questions or concerns about your rights as a research participant, you can contact the Officer for Research Integrity at (304) 388-9913. You may remain anonymous if you wish.

Additional Information and Details

What will you be asked to do?
In addition to the study events described above, you will be asked to follow standard instructions relating to your procedure and recovery given to you by your physician.

What are the risks involved in the study?
In addition to the study risks described above, we want you to know the following: Participation poses minimal risks, including potential loss of confidentiality.

How will my information be protected?
In addition to the protections described above, we want you to know the following:
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.

Could my information be used for future research without asking for my additional permission?
Yes. If all identifiers (name, date of birth, etc.) are removed, it is possible that the data collected for this study may be used for future research studies or distributed to another investigator for future research studies without your additional consent but not without permission from our Institutional Review Board.

Will you be given the results of any study tests or procedures that are done?
You will receive results from your procedure as you normally would when they are available. The measured outcomes of this study are based on your answers to the survey questions, and, as such, there will be no reportable results.

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What will happen if you decide to withdraw from the study?
If you decide to leave the study, contact the researchers so they know. The researchers may ask you the reason, but you are not required to provide it.

After you leave the study, no new information collected will be used for research purposes. Information that has already been collected prior to withdrawing will remain in the study database and be used to determine the results of the study.

If you want to volunteer to be in this research, please sign below.

Signature

You understand the purpose of this study, what will happen, the possible benefits, and any risks. You have received a copy of this form and had a chance to ask questions before signing. You know you can ask more questions at any time. You choose to take part in this study willingly. You also agree to let the researchers use and share your health information as explained in this form. Signing this form does not take away any of your legal rights.

_____ _____
Signature of participant Date

_____ _____
Signature of person obtaining or verifying consent Date

_____ _____
Witness Signature Date

(A witness signature is only required if the consent form is to be read to the subject. In all other instances, the witness signature should be left blank.)