University of Arkansas for Medical Sciences Informed Consent Form

- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can quit the study at any time.**
- **Please take as much time as you need to make your choice.**
- **You can still get your medical care from UAMS even if you are not in the study.**

Why am I being asked to be in this research study?

- We want to learn more about using a video before surgery as a pain management education tool, compared to written or verbal pain management education, to teach patients about ways to control their pain after surgery.
- This study will help us learn more about pain medicine consumption after surgery.
- We are asking people like you who do not use opioids every day and are scheduled for one-day surgery to help us. 110 people 18+ years old will be part of this study at UAMS.

What if I don't understand something?

- This form may have words you don't understand. Research staff will read it with you, if you like.
- You may ask as many questions as you like before you decide whether you want to be in this study.
- You are free to ask questions at any time before, during, or after you are in the study.

What if I say yes, I want to be in this study?

We first will see if you qualify to be in the study. We will:

- Make sure you are scheduled for surgery

If you qualify, we will do these things:

- Make sure you have not taken opioid pain medication in the past 30 days

- Assign you randomly (like the flip of a coin) to one of two study groups:
  1. Shown a 5-10 minute video on an IPad at bedside in pre-operative area, or
  2. Standard treatment, showing no video.
- Call you 7 days following your surgery and ask you about how many days you have taken opioids for pain, your thoughts about the opioid education you received, your knowledge of opioids and opioid safety before and after the hospital visit, and your satisfaction with your postsurgical experience.
- Call you 30 and 90 days following your surgery and ask you about your opioid use and post-operative pain condition. Phone calls should not exceed 5 minutes.
- Will access the Arkansas Prescription Drug Monitoring Database to check your drug refill to see what medications were prescribed or refilled for your pain during the 90 days after surgery.
- If you are assigned to the video group, we may ask you to participate in one of two focus group discussions on the UAMS campus to talk about your thoughts on the video. They will last about one hour and ask for opinions on the video and areas of improvement. Focus groups will be audio recorded.

How long will this study take?

The entire study will take about 12 months. The expected start date of January 2019 and end date of December 2019. Your individual study participation will include one visit (the day of surgery), follow-up telephone calls 7-, 30-, 90-days after surgery and your return for one focus group if desired.

Who will see the information about me that is collected?

- The local study team will know your name and have access to your information.
- If you join a focus group, other group members will know who you are and may learn things about you. We will let the focus group participants know that everything said in the group will be kept confidential.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will take your name off of information that we collect from you during the study.
- When we share the results of the study in medical journals, we will not include your name or patient identifiers.

- There are people who make sure the study is run the right way. These people may see information from the study about you. They are
  - ✓ TRI (Translational Research Institute)
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ UAMS Institutional Review Board
  - ✓ Other institutional oversight offices
- State law requires we tell the authorities if we learn
  - ✓ about possible child or adult abuse
  - ✓ that you might hurt yourself or someone else

Where and how long will my information be kept?

- We will code your information and keep the code in a locked file cabinet.
- Only investigators will have access to the code for your information.
- We will not put information about you from the study in your medical record.

What if I say no, I do not want to be in this study?

- Nothing bad will happen.
- You will still get medical care at UAMS.

What happens if I say yes, but change my mind later?

- You can stop being in the study at any time.
- Nothing bad will happen.
- You can still get medical care at UAMS.
- If you decide to stop being in the study, call Dr. Johnathan Goree at 501-686-8818.

Can I be taken out of the study even if I want to continue?

Yes, the study doctor (or head researcher) can take you out of the study if:

- You do not follow study instructions.
- It is not in your best interest to continue.
- The study is stopped for any reason.

If I stop being in the study, what will happen to any information collected from me in the study?

- If you wish to have your information taken out of the study, call Dr. Johnathan Goree at 501-686-8818

Will my information from the study be used for anything else, including future research?

- Yes. Results will be used to improve opioid video and create a larger study to determine if video intervention decreases rates of chronic opioid use, chronic post-surgical pain conditions, and decreased days to opioid cessation. Information will be deindentified.
- Coded information will be stored in a locked file cabinet in the primary investigators office for up to 7 years.
- If you wish to have your information taken out of the study, call Dr. Johnathan Goree at 501-686-8818.

There will be a place at the end of this form for you to say whether

- **You agree that your information collected in this study may be used in future research.**

Will it cost me anything to be in the study?

The study will not cost you anything. You or your insurance company will be responsible for your regular medical care as usual.

Will I be paid?

Yes. We will give you$20. This is to thank you for your time. We will give it to you after completion of the phone call at 90 days in the form of a gift card that will be mailed to you. If you participate in a focus group, we will give you a $50 gift card to thank you for your time and inconvenience. If you change your mind and decide not to be in the study, you will pro-rated for the parts you completed ($5 for day 7 phone call completion, $5 for day 30 phone call completion, and $10 for day 90 phone call completion.)

Will being in this study help me in any way?

Being in the will not help you, but may help people with post-operative pain control and outcomes in the future. What we learn may help in the following ways:

- Teaching of post-operative pain control options

- Reduced anxiety related to post-operative pain potential
- Decrease risk of chronic opioid use starting after surgery

What are the risks of being in this study?

The risks are:

- The risks for this study are no more than what happens in everyday life.
- Someone could find out that you were in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy.
- The questions could make you sad or upset.

What are the alternatives to being in this study?

You do not have to be in this study. There are no alternatives to being in this study.

What if new information comes up about the study?

- We want you to know about anything that may change your mind about being in the study.
- The researcher will let you know by:
  - ✓ calling you
  - ✓ sending you a letter
  - ✓ telling you at a follow up visit

Where can I find more information about this clinical trial?

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 any time.

What if I have questions?

- Please call the head researcher of the study Dr. Johnathan Goree at 501-686-8818 if you
  - ✓ have any questions about this study
  - ✓ have questions about your rights
  - ✓ feel you have been injured in any way by being in this study
- You can also call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if you

- ✓ have questions about this study
- ✓ have questions about your rights
- ✓ can't reach the study team
- ✓ need to speak to someone not directly involved with this study

What should I do if I want to be in the study?

Sign this form. We will give you a copy of this form to keep.

By signing the document I am saying:

- I understand that joining this study is voluntary.
- I agree to be in the study.
- Someone talked with me about the information in this document and answered all my questions.
- I have been asked if I wish to talk directly to the study doctor.

I know that:

- I can stop any and all parts of the study at any time and nothing bad will happen to me.
- I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- My decision will not change my medical care at UAMS.
- I do not give up any of my rights by signing this form.

I agree to be part of this study:

_____ _____

Your name (please print) Your signature

_____

Date

_____ _____

Name of person obtaining consent (please print) Signature of person obtaining consent

_____

Date

I agree to being contacted for the focus group research related to this study.

___ YES ___ NO

_____ _____

Your name (please print) Your signature

_____

Date

My information collected in this study may be used in future studies related to the present research.

___ YES ___ NO

_____ _____

Your name (please print) Your signature

_____

Date