Opioid Reduction Program for Total Knee Replacement Patients Main Consent Form

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TITLE: Opioid Reduction Program for Total Knee Replacement Patients

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1. KEY INFORMATION:

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

Current research suggests that greater exposure to opioids (in terms of medication strength and length of use) is related to risk of later misuse. The purpose of this study is to examine the effectiveness of an opioid reduction program (ORP) a behavioral intervention in total knee replacement (TKR) patients. We will be comparing this intervention to standard treatment as usual (TAU).

Procedures:

In this study, we will randomize subjects between different treatments to compare their efficacy and safety. We will also be collecting data from your medical record as you complete visits for your clinical care, and we will be asking you to complete some additional questionnaires about your opioid use following surgery.

You will be randomly assigned (like the flip of a coin) to receive TAU or ORP. You have a 1 in 2 chance of receiving ORP, the experimental treatment. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. It is not known whether the experimental treatment is as good as, better than, or worse than the standard treatment.

Your participation in this study will last until approximately 12 weeks after your surgery.

You will have a total of 3 assessment visits including today. These visits will last approximately 30 minutes. If you are assigned to the ORP group, you will receive an additional 15-minute phone call 2-weeks after surgery to review information from the intervention.

The following procedures are being performed for research purposes only:

- Copying information such as your surgery notes and prescription information from your medical record;

- 3 or 4 visits with study staff (depending on which group you are assigned to);
- 27 questionnaires across the three visits (including demographics, opioid use, and pain management).

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLOWED.

Risks:
Some of the most common side effects from study participation are uncomfortable feelings or tiring during the questionnaires.

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:
The results of this study may help people having total knee replacement in the future by decreasing the amount of opioid they take post-surgery which could reduce their risk for opioid use disorder.

Alternatives:
You cannot receive the ORP intervention without participating in this study. You will receive medical treatment for your total knee replacement whether or not you participate in the study.

If you do not participate in this study, none of the procedures described in this consent form will be performed.

Voluntary Participation:
Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you are a student of UTHSC, participating or not participating in this study will in no way influence your grade in any course. If you are a resident or fellow of UTHSC or Cambpell Clinic, participating or not participating in this study will in no way influence your academic standing. If you are an employee of UTHSC or Cambpell Clinic, participating or not participating in this study will not affect your employment status.

2. DETAILED PROCEDURES TO BE FOLLOWED:

Approximately 100 subjects will be participating in this study.

The study will take place at Campbell Clinic (1400 S Germantown Rd., Germantown, TN, 38138) and UTHSC Department of Preventive Medicine (66 N. Pauline St, Memphis, TN 38163).

Baseline Visit (all participants, this will take an additional 20-30 min. today):

- Complete 9 questionnaires
- ORP arm only — receive behavioral intervention regarding opioid use
    - The intervention will be audio recorded. The recordings will be stored electronically on a secured server and labeled with your subject ID number, not your name.

Booster Visit (ORP arm only; 10 minutes over the phone approximately 2 weeks after surgery)

- Review intervention information with study staff member
    - The intervention will be audio recorded

4-Week Follow-Up (all participants, 20 minutes over the phone 4 weeks after surgery)

- Complete 9 questionnaires

12-Week Follow-Up (all participants, 20 minutes over the phone 12 weeks after surgery)

- Complete 9 questionnaires

Your participation in this research study may be stopped by the study doctor without your consent for any of the following reasons:

- If you do not show up for visits

If you decide to stop being part of the study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner. You may ask that your identifiable data be destroyed.

3. RISKS ASSOCIATED WITH PARTICIPATION:

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

Questionnaires/Surveys:
Completion of the opioid use surveys may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions and you may take a break at any time during the study.

Audio Recording:
Having your voice recorded may make you feel uncomfortable. You may take a break during any time of the study. There is also a potential risk of loss of confidentiality that someone who listens to your audio recording might identify you.

4. CONFIDENTIALITY:

Research records
All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Identifiers might be removed from your private information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Medical Records
Information about your participation in this study or the results of procedures performed in this study will not be placed in your medical record.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

Limits to Confidentiality
Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records

- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- The Tennessee Clinical and Translational Science Institute (TN-CTSI) which sponsors and provides funds for this research

However, some of these organizations or institutions above do not have the same obligations to protect your PHI.

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

5. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee, Cambpell Clinic, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Cambpell Clinic do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Cambpell Clinic do not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide you with a subsequent referral to appropriate health care facilities.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

6. QUESTIONS:

Contact Kristen Barnett, Research Assistant, at 901-448-1247 if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury, contact Dr. William Mihalko at 901-759-3100. This is the Campbell Clinic main line that goes to an answering service after hours.

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

7. PAYMENT FOR PARTICIPATION:

You will receive a $25 gift card to Amazon at the completion of today's visit and the 4-week visit. You will receive a $50 gift card to Amazon at the completion of the 12-week visit. If you complete all the study visits, you will receive a total of 3 gift cards worth $100.

8. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study.

9. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.
- A text message will be sent to the phone number you provided us.
- An email will be sent to the email address you provided us.

Put your initials on one of the lines below:

_____We CAN attempt to find/contact you in the above ways.

_____We MAY NOT attempt to find/contact you in the above ways.

10. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____ _____ _____
Signature of Research Subject (18 years +) **Date** **Time**

_____
Printed Name of Adult Research Subject

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

_____
Printed Name of Person Obtaining Consent

In my judgment, the subject has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____ _____
Signature of Investigator **Date** **Time**