INFORMED CONSENT FORM
COVER SHEET

Title: Self-reported Usage Patterns of Opioid Analgesic Medications After Surgery

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Invitation to participate in the research study: Self-reported usage patterns of opioid analgesic medications after surgery

Principal Investigator: Karsten Bartels, M.D.
COMIRB No: 14-1938
Version Date: 10/17/2017

Dear [first_name_idef] [last_name_idef],

You are being asked to be in this research study because you recently had surgery or will have surgery at the University of Colorado Hospital.

If you join the study, you will be asked to complete a brief questionnaire asking about your pain management every week for the first four weeks after hospital discharge. Each of the four surveys will take about 10 minutes to complete. You can complete the survey by filling out a hard copy form, online, or by phone, whichever is most convenient for you. The first 10 respondents will receive a follow-up email or phone call to ask about any difficulties understanding the survey questions. We will also access your Electronic Medical Record at the University of Colorado Hospital to get demographic data, information on what type of surgery was performed, prescribed and non-prescribed medications, and additional clinical information that may potentially affect how your pain was managed.

This study is designed to learn more about use of prescribed opioid pain medications after surgery. In the future, we would like to better estimate how much medication patients actually need. Possible discomforts or risks include feeling uncomfortable with the questions asked. There may be risks the researchers have not thought of.

Every effort will be made to protect your privacy and confidentiality by storing all responses in a secure database with password protection limiting access to study personnel only. At the end of the study any link between your identity and the responses will be destroyed.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of information about current child neglect or child abuse or if you tell researchers that you are going to harm yourself or others. Those things must be reported to the proper authorities to keep you or others safe.

This research is being paid for by the University of Colorado, Department of Anesthesiology and the National Institutes of Health, a federal agency. Participants will receive a $10 gift card or an equivalent money order if so desired ($40 total for all four surveys). If you leave the study early, or if we have to take you out of the study, you will be paid, but not the full amount.

You have a choice about being in this study. You do not have to be in this study if you do not want to be. We may also contact you in the future to ask if you would be willing to participate in other research studies, but you do not have to participate in any other studies if you don't want to.

If you have questions, you can call the study doctor Karsten Bartels, M.D., at 303-724-0333 or email him at: **karsten.bartels@ucdenver.edu** You may also contact the Study PRA, <INSERT PRA NAME>, at <INSERT PRA NUMBER> or <INSERT PRA EMAIL>@ucdenver.edu. You can call/email and ask questions at any time.

You may have questions about your rights as someone in this study. If you have questions, you can call the COMIRB (the responsible Institutional Review Board). Their number is (303) 724-1055. By completing the contact information form, you are agreeing to participate in this research study.

Thank you for your time.

Warmest regards,

Karsten Bartels, M.D.
Assistant Professor of Anesthesiology, Medicine, and Surgery
University of Colorado Denver