Title: Mobile-Based Contingency Management to Promote Daily Self-monitoring in Primary Care Patients

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: PROMOTING MONITORING: A PILOT TEST

VCU IRB NO.: HM20013828

SPONSOR: VIRGINIA COMMONWEALTH UNIVERSITY PSYCHOLOGY DEPARTMENT

You are being asked to be part of a research study. This form describes the study in order to help you decide whether to participate in the study. Please read this form carefully and ask the study staff about anything in this form that you have questions about or do not understand.

You may refuse to take part in this study or withdraw from this study at any time.

VOLUNTARY PARTICIPATION

Your participation is voluntary. You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

PURPOSE OF THE STUDY

The purpose of this study is to test a strategy to help increase the completion of daily surveys related to pain experience. The information you provide will help determine if the strategy is helpful in promoting survey completion, and how completing daily surveys may be helpful to you.

You are being asked to participate in this study because you are at least 18 years of age, are not pregnant, own a smartphone (iPhone or Android device), have had non-cancer related chronic pain (consistent daily pain) for 3 months or greater, and have been prescribed one or more opioid medication(s) for pain management.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to participate in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen during this study.

This research study will evaluate approximately 80 subjects, 18 years of age or older who own a smartphone, have had non-cancer related chronic pain for at least 3 months, are not pregnant, and have been prescribed one or more opioid medication(s) for pain management.

In this study, you will be required to complete 30-45 minutes of questions about pain, medication use, and health. After you complete the survey, we will contact you for brief Zoom or telephone call to set up the app, review handouts, etc. You will then be assigned to a **Daily Survey** or **Daily Survey + Contingency Management (CM)** group. Your chances of being assigned to either group are random, like “flipping a coin.” Then, you will download the DynamiCare smartphone app to your phone. Regardless of which group you are assigned to, you will have an opportunity to complete daily surveys on this smartphone app. There will also be a 28-day follow-up questionnaire, which should take approximately 30-45 minutes. In total, it

will take 30 days to complete participation in this study (study completion occurs once the 28-day follow-up visit has finished).

If you are assigned to the **Daily Survey** group, you will be asked to complete a brief survey with questions related to pain experience every day for 28 days. This daily survey will take approximately 5 minutes to complete. You will be asked to access and complete the daily surveys on the DynamiCare smartphone app. This app will also send you daily reminders to complete the daily surveys. If you are assigned to the **Daily Survey + CM** group, you will complete the same daily surveys, but in addition, you will have an opportunity to win money for completing daily surveys. The DynamiCare smartphone app will keep track of these opportunities to win money for completing daily surveys.

All participants will also be asked to complete questionnaires at the end of the study. The questionnaires will collect information related to your pain experience, health, medication use, and what you think about completing the daily surveys.

At the 28-day follow-up visit, you will have the option to be sent a printout summarizing your daily survey information. Other than this printout, we will not give you any other individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

RISKS AND DISCOMFORTS

Few risks are expected by taking part in this study. There is minimal risk with completing surveys. Talking about some topics can cause people to become anxious or upset. You do not have to answer any questions you do not want to, and you may stop participation at any time. If you become upset, the study staff will give you names of people to contact so you can get help dealing with the things that upset you.

You may be disappointed if you are not assigned to the **Daily Survey + CM** group condition and are not provided with the opportunities to win money for completing daily surveys throughout the study.

Your information is considered confidential. Your answers will not be shared with anyone outside of our research team. To further protect your confidentiality, we have obtained a federal certificate of confidentiality from the federal government. This further protects the information you provide during the study so that it cannot be obtained by your health care providers or others outside the research team.

BENEFITS

While there are no direct benefits from participating in this study, you may benefit from completing the daily surveys related to your pain experience. The information that we learn from participants in this study may help us to improve our understanding of pain experience and how to better manage pain in people who have chronic pain.

COSTS

As you will be asked to download an app onto your cellphone, you will incur data usage costs during the 28-day daily survey period. The app requires about 155 MB of free hard drive space on your cellphone for install and usage. There are no other costs to you for participating in this study other than the time you spend in the study.

PAYMENT FOR PARTICIPATION

All study participants will earn equal amounts of compensation for their time and efforts for completing research assessments. This includes a $20 Amazon e-gift card for baseline assessment and a $30 Amazon e-gift card for the 28-day follow-up assessment.

Also, if you are assigned to the **Daily Survey + CM** group, you will have the opportunity to win money for completing daily surveys. For example, when you complete a daily survey from above, you will be able to draw from a "fishbowl" on the smartphone app with different monetary values. Any money you receive from these draws will be automatically loaded onto a study debit card provided to you by the research staff. The number of draws you earn will increase by one with each back-to-back completed daily survey (capping at 10 draws). Failure to complete a daily survey, however, will result in a reset to one draw per survey.

Total payments within one calendar year that exceed $600 will require the University to annually report these payments to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

ALTERNATIVES
You can choose not to participate in the study.

CONFIDENTIALITY
We will not share what you tell us with anyone, including your provider, and your answers on the surveys will be kept private; however, information from the study and the consent form may be looked at or copied for research or legal purposes by Virginia Commonwealth University.

The hard-copy information you give us will be stored in a locked cabinet, in a locked office. The information you provide through the app or the computer survey will be stored on a secure and confidential server. We will not tell anyone what you say while participating in the study or on the questionnaires. We have a Confidentiality Certificate from the National Institutes of Health. It means that researchers cannot be forced to identify you, even under a court order or subpoena. The Certificate adds special protection for research information that identifies you. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

You should know, however, that researchers must tell someone if you tell us that you may cause harm to yourself, harm to others, or if child or elder abuse becomes a concern. In that case we may talk with you and, if possible, try to find a way to help with your needs. Also, the agency that pays for this study or Virginia Commonwealth University may see your information in an audit, but they too will protect your privacy. What we find from this study may be presented at meetings or published in papers, but your names will never be used in these presentations or papers.

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 Website will include a summary of the results. You can search this Web site at any time.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

Dace Svikis, Ph.D.
Virginia Commonwealth University, Institute for Women's Health
Theater Row Building
4th Floor, Suite 4200
730 E. Broad Street
Richmond, VA 23219
(804) 827-1184

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298-0568
(804) 827-2157

You may also contact this number for general questions, concerns, or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at http://www.research.vcu.edu/irb/volunteers.htm.

Please select one of the following:

☐ Yes, I understand this and want to participate in the PROMOTING MONITORING: A PILOT TEST study.

☐ No, I do not want to participate in the study. (Participant will see "Thank you for your time! Please close this browser window.")