Title: Web-Based CBT (Cognitive-Behavior Therapy) for Opioid-Treated, Chronic Pain Patients with Aberrant (Problematic) Behavior

Sponsor: XXXX.

Principal Investigator: XXXX

Address: XXXX
Telephone: XXX-XXX-XXXX

1. WHY IS THIS STUDY BEING DONE?

You are invited to participate in this research study in order to help us develop a computer-delivered psychosocial intervention for chronic pain patients who are prescribed opioids and having problems with their pain medication. Problems with pain medication represent a range of behaviors such as not taking medication as prescribed, emergency room visits, borrowing medication from others, problems controlling anger and difficulty thinking clearly.

You are eligible to participate in this study because you are a patient at XXXX, are prescribed opioids and report problematic opioid related behavior.

This study is being conducted by XXXX and XXXX and is funded by XXXX.

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

In this study, you will be asked to participate in one focus group session with other pain patients. In this focus group, you will be asked for your opinion about the best ways to use an interactive, computer program to teach pain patients about several topics that are related to effective management of chronic pain. Topics for discussion may include: strategies for pacing activities such as exercise and rest, managing negative moods, ways to combat fatigue, relaxation and problem solving. You do not need to have previous experience with a computer.

Additionally, you may be asked to provide input on other aspects of the computer-delivered, psychosocial treatment program, including a storyline and characters, graphics and video to integrate various sections of the program. You will be asked to discuss each of these topics one at a time during the focus group. The focus group session will last about 1.5 hours (about 90 minutes).

The information that you provide during the focus group will be used in developing text, graphics and video clips that will be included in a computer-based psychosocial treatment program for chronic pain patients who are prescribed opioid medication. As a result, when talking about each topic of the program, you will be asked to discuss 1) the kinds of characters and scenarios that can best illustrate the topic, including the conversation or scripts to be used by the actors/actresses in the skits, 2) the type of music and props that should accompany the various scenarios, as well as 3) the type of graphics and/or animation that should be available on the computer screen along with the videos.

The focus group in which you participate will be recorded on audio digital tapes so that the content of the focus group discussion may be used to design program content. The digital recordings will be password protected and will be stored on computers at XXXX. The audio files will be destroyed within 3 years after this study is completed.

3. WHAT ABOUT THE AUDIO TAPES?

You and other study participants and the focus group facilitator will be instructed not to mention any information that could identify you (or any other participant). If anyone accidentally does so, that information will be deleted from the recording.

When completed, digital audio files will be identified by code numbers only; your name will not appear in the files. The digital recording will be securely stored on computers and only members of the staff of the Project will have access to them. Code numbers will be secured on a separate password protected file and, as a hard copy, will be locked in a file drawer.

These audio recordings will only be used to help shape development of the computerized program and will not be used outside the project.

Employees of the Agency funding the research project may conduct audits or reviews. If so, they may listen to the recordings to review or verify data. If they do so, they will use the code numbers only; they will be unable to identify you.

All recordings will be destroyed three years after the completion of the Project.

4. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About XX patients from the pain clinic at XXXX will be asked to participate in one of three focus groups; each focus group will have about 8 participants.

5. HOW LONG WILL I BE IN THIS STUDY?

If you choose to take part and are found eligible for this study, you will participate in 1 (one) single session lasting about 90 minutes.

6. WHAT ARE THE RISKS OF THE STUDY?

One risk of participating in this study is that you may feel uncomfortable talking about the planned topics, such as not taking medication as prescribed or using alcohol or drugs that your physician did not prescribe. Also, there is a risk of loss of confidentiality, in which you may become known to be associated with this study to individuals outside of the research team. You may also feel uncomfortable having the focus group session audio-taped.

In addition, please understand that if you do not want to discuss a particular topic in the focus group, you may choose not to do so. If you chose to not discuss a particular topic, you can continue in the rest of the session without any penalty. Also, you can choose to withdraw from the focus group at any time before completing it.

7. ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

The possible benefit of your participation in this study is that you may learn more strategies to effectively manage your chronic pain than you may already know. This information may help you to understand how certain types of thoughts, feelings and behavior affect your pain severity and your reaction to it. In addition, your participation may help us in developing a computer-based psychosocial treatment for chronic pain patients.

8. WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

You do not have to be in this research study. You can still have medical care at XXXX without being in the study.

9. WHAT ABOUT CONFIDENTIALITY?

Please understand that we will make every effort to ensure that all the information that you provide in the focus group will be kept confidential. This means that all of your responses in the focus group will be coded by a study number and not by your name. The study results will be stored in a locked cabinet and any study information stored in a computer will be password protected. Only the study staff will have access to the study results. Research staff is carefully trained to maintain the confidentiality of study participants. However, we cannot guarantee absolute confidentiality.

Your personal information also may be used and disclosed in the same ways that it may be used and disclosed for regular hospital treatment, payment and health care operations: for example, with your insurance company so that, as appropriate, you may get reimbursed or covered for any medical services you receive.

If you consent to participate in this research, your personal information will be kept confidential and will not be released without your written permission, except as described in this section or as required by law. Your personal information may be shared, to the extent necessary, among the research staff, with the Institutional Review Board and research oversight staff, and/or with your treating physician or your other health care providers.

Your name will not be reported in any publication; only the data obtained as a result of your participation in this study will be made public. If this study involves medications or devices regulated by the Food and Drug Administration (FDA), the FDA and other regulatory agencies, as well as the sponsor of the study, may inspect records identifying you as a subject in this investigation.

If you decide to participate, the study staff will ask for your separate written permission, on a form called a "Research Authorization," for your permission to use and share your personal health information for purposes related to the study and as required by law.

Certificate of Confidentiality

A Certificate of Confidentiality will be applied for from the Department of Health and Human Services. The Certificate prevents Investigators and other project staff from being forced, even by court order or subpoena, to reveal that you are in the project or to release any research data by which you may be identified. The Certificate does not prevent the Investigators and other project staff from releasing such information, but it would only be released according to both the strict confidentiality procedures of XXXX and the rules of ethical research practice under the following circumstances:

- If you provide information in the research interview of any clear and present danger to yourself or others, such as serious thoughts of suicide, current or future child abuse, intended assault or similar crimes, such information may be released by one of Principal Investigators (or their designee) without your consent to the appropriate agency.

- If you are currently a patient at XXXX and information from your research interview may be of benefit to your treatment, that information may be released by one of Principal Investigator (or their designee) only with your consent to the appropriate professional staff of your program.

10. WHAT ARE THE COSTS TO ME?

There will be no cost to you for taking part in the study.

11. WILL I RECEIVE ANY REIMBURSEMENT?

You will receive $XX in cash as reimbursement for your time and effort at the completion of the focus group session.

12. WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Taking part in this study is completely up to you. You may choose not to take part in this study or you may choose to leave the study at any time. The care you receive at XXXX or from your regular doctor will not be affected by what you decide.

We will tell you of any new information that develops during this study and that may affect your health, welfare or willingness to stay in this study.

You will receive a signed copy of this informed consent form.

13. WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions about this research study, please contact either XXXX or XXXX, Principal Investigators at XXXX, at XXX-XXX-XXXX or XXXX, at XXX-XXX-XXXX

If you have any questions about your rights as a research subject, please contact XXXX, at XXX-XXX-XXXX.

Your signature on page 1 of this form means that you choose to take part in this study.