Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Lindsey C. McKernan, Ph.D. **Revision Date: 1 August 2018**
Study Title: Chronic Pain Skills Study

This informed consent document applies to: Adults

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

1. **Purpose of the study:**
   The purpose of the study is to examine the impact of a hypnosis program on reducing pain, suffering, and improving quality of life for those we serve at the Osher Center for Integrative Medicine (OCIM). You are being asked to participate in this research study because you have expressed interest in clinical hypnosis for pain at OCIM and qualify for this service.

2. **Procedures to be followed and approximate duration of the study:**
   If you elect to participate in this study, you will be asked to complete a series of questionnaires along with the treatment we will be providing. You will have the option of completing these questionnaires 1) online, 2) via computer at OCIM, or 3) on paper. This will take approximately 20-30 minutes and you will be asked to complete these questionnaires before, after, 3-, and 6- months following receiving this service (at four different time periods). The last week of treatment, we will also be conducting a formal assessment of your responsiveness to hypnosis.

3. **Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:**
   The risks of participating in this study are minimal. Some of the questionnaires you will be asked to complete include questions about stressful life events and your current emotional state. These questions may cause some temporary emotional discomfort. You do not have to answer questions that you do not feel comfortable answering. Sitting for extended periods of time may lead to physical discomfort or stiffness.

4. **Good effects that might result from this study:**

   a) The benefits to science and humankind that <u>might</u> result from this study. The potential benefits of this study are to assist in providing an evidence base for this specialized service, potentially widening access to this service through further dissemination, education, and training. In addition, participation in this study could provide new information about how hypnosis impacts health and wellbeing.
   b) The benefits you might get from being in this study. There may be no direct benefit from participating in this study.

5. **Compensation for participation:**
   You will be compensated $10 for your participation in each assessment before, after, and at 3- and 6- months after treatment (up to a total of $40) in the form of a gift card. Compensation will be made

available following study completion. We may ask you for your Social Security number and address before you are compensated for taking part in this study.

6. **Circumstances under which the Principal Investigator may withdraw you from study participation:**
Although unlikely, the Principal Investigator may withdraw you from the study if you are determined to be taking medications or have certain conditions that may interfere with the accuracy of test results. We check for this information prior to offering you the opportunity to participate in this research, and this would happen only in the rare circumstance that this information had been missed or recorded incorrectly. This will not effect compensation for your participation and you can still receive the clinical service even if this occurs.

7. **What happens if you choose to withdraw from study participation:**
If you decide to stop being part of the study, you should inform Dr. McKernan. Deciding to not be part of the study will not change your regular care at OCIM or relationship with Vanderbilt University Medical Center in any way.

8. **Contact Information.** If you should have any questions about this research study or possibly injury, please feel free to contact **Lindsey C. McKernan, Ph.D.** at **(615) 875-9990.**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. **Confidentiality:**

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Records related to the study will be stored and maintained on-site via computer and secured at all times by Dr. McKernan and her research team. Dr. McKernan will store protected health information and/or identifying information in a separate database, assign a number to your responses, and be the only person who has the key to indicate which number belongs to which participant. Dr. McKernan is also requesting permission to contact you to potentially offer participation in future research studies. Any articles or presentations that result from this research will heavily disguise or conceal personal information to maintain confidentiality.

14. **Privacy:**

Privacy of Protected Health Information:
As a part of this study, if you are being treated at Vanderbilt University Medical Center (VUMC), we are asking for permission to access your VUMC medical record for review. From your medical record, we will be gathering information related to current medication usage, diagnosis, treatment history, and your healthcare usage over the past 24 months. All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. McKernan and her study team may share the results of your study and/or non-study linked medical information, questionnaire results, healthcare utilization, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal

Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, the National Institute of Health, or other potential sponsors to support future studies. In addition, off-site collaborators at regional universities (e.g. Washington University School of Medicine) may have access to a limited data set resulting from this study, which uses PHI without direct identifiers. These individuals have signed formal Data Use Agreements with Vanderbilt in compliance with HIPPA and the HITECH Act. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. McKernan and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. McKernan in writing and let her know that you withdraw your consent. Her mailing address is 3401 West End Avenue, Suite 380, Nashville, TN 37203. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title