Consent and Authorization Form

Protocol #: 20-1576
Project Title: Pilot Trial of Hypnosis and Enhanced Communication Training to Reduce Anxiety, Improve Patient Satisfaction, and Decrease Movement for Patients Undergoing Magnetic Resonance Imaging
Principal Investigator: Alexandra Chadderdon, PsyD
Co-Investigator: Justin Honce, MD
Version Date: 07/14/2020

You are being asked to be in a research study at the University of Colorado Hospital (UCH). This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

The study is being conducted to find ways of helping patients to be more comfortable during MRI. You are being asked to be in this research study because you are already scheduled to receive clinical examination using MRI as part of your care at UCH. Up to 80 UCH patients will participate in the study.

What happens if I join this study?

If you decide to join the study, you will be randomly assigned to either one of the following: 1) undergoing MRI as usual, 2) undergoing hypnosis aimed to enhance comfort prior to and during MRI, or 3) undergoing MRI by a technician who has been trained in enhanced communication skills aimed to increase comfort during MRI. Each session will lasts approximately up to 3 hours, which is a typical length for MRI scan for standard care (as tailored for the type of specific treatment that you need). During the MRI scan, your oxygen saturation levels will be measured using a pulse oximeter. This device is non-invasive because it fits onto your finger similar to a clip-on device. It will snugly cover one of your fingers throughout the MRI scan and it will automatically take readings of the levels of oxygen in your blood. As part of the study, relevant information from your medical record will also be collected and you will be asked to fill out several questionnaires before and after the MRI scan.

What are the possible discomforts or risks?

While participating in this study, you may potentially experience drowsiness or dizziness due to the hypnosis, discomfort in having a device covering your finger (i.e., the pulse oximeter) throughout the MRI scan, and discomfort in sharing your feedback when filling up the assessment questionnaires. With any study involving medical record and direct data collection, there may be a risk associated with breach of confidentiality.

To address these possible discomforts or risks, the Principal Investigator (Dr. Alexandra Chadderdon) will be present throughout the study to monitor your condition. In the event that any psychological concerns arise, a list of mental health resources will be provided to you. There are no physical risks to participating in this study. All MRI procedures will follow standard

clinical care. The use of pulse oximeter device is also a standard procedure for measuring the levels of oxygen in the blood. The device is non-invasive, not tight fitting, and can be easily removed if needed.

You do not have to answer any questions in the assessment that make you feel uncomfortable. You may choose to stop participating in the study at any point.

There is a risk that people outside of the research team may see your research information. We will do all that we can to protect your information by ensuring that all your data are stored and managed in secure, encrypted, and password-protected databases and servers. You will also be assigned a randomly generated study ID, which will be used to replace your name in all of your responses. This is done to further ensure confidentiality. None of the responses you share and other data about you that is collected during the study will be linked to your name.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about ways to increase patients' comfort during MRI. There is no direct benefit to study participants.

Will I be paid for being in the study? Will I have to pay for anything?

It will not cost you anything to be in the study. You will not be paid to be in the study.

However, the MRI portion is part of your clinical care. Due to that, you will be billed for the service following UCH standard billing policy.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

The researchers carrying out this study are Alexandra Chadderdon, PsyD (as Principal Investigator) and Justin Honce, MD (as Co-Investigator). You may ask any questions you have now. If you have questions later, you may call Dr. Chadderdon at 303-724-4987 or Dr. Honce at 720-848-8154.

You may have questions about your rights as someone in this study. You can call Drs. Chadderdon and Honce with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

Consent and Authorization Form

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and the health systems it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Hospital (UCH)

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate health systems may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Alexandra Chadderdon, Psy.D.
Fitzsimmons Building Mail Stop F546
13001 E 17th Place
Aurora, Colorado 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.

Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Consent and Authorization Form

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Responses to questionnaires that will be administered during this study

What happens to Data, Tissue, Blood and Specimens that are collected in this study?

If you join this study:

- The data that is collected will be stored in a secure HIPAA compliant data base for research purposes. Any personal health information that is collected will be kept separate from other non-identifiable data and will be destroyed after 7 years, in compliance with research guidelines. Any paper copies of data from surveys will be shredded after they are entered into the secure research data base. No bodily tissues, blood, or other specimens will be collected for this study.

Consent and Authorization Form

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:

Date:_____

Print Name:_____

Consent form explained by:

Date:_____

Print Name: _____

In the event of seeking consent of non-reading subjects, please complete the following in addition to the above:

_____ Date_____

Print Name: _____

Witness of Signature ☐

Witness of consent process ☐