**BROWN UNIVERSITY**

**MRI RESEARCH FACILITY INFORMED CONSENT ADDENDUM**

[Title of study]

[*For multi-consent studies*: List the sub-title that identifies the specific population or activity covered by this consent.]

Addendum

[Version #, date]

* **OVERVIEW**You are being asked to be in one or more Magnetic Resonance Imaging (MRI) scans for research. This document will give you important information about MRI scans, let you know what to expect when the MRI scans are done, and tell you how researchers will protect your safety.
* **BEFORE YOU GO IN THE MRI SCANNER**The MRI scanner uses a powerful magnet to take pictures of your body. MRI is generally considered safe but because of the strong magnetic force it may be dangerous to go into the MRI scanner if you have metal in or on your body or have certain medical devices, such as a pacemaker. Therefore, you will have to follow certain rules and answer some questions to make sure you can safely have an MRI scan. Before you have your MRI scan you will be asked to complete a checklist that asks you questions about your medical history. You will also be asked about any metal you might have in your body. For your safety, it is important to answer all of the questions as accurately and truthfully as you can. A researcher will go over the checklist with you.

**If you are able to become pregnant:** Researchers do not know the safety of MRI during pregnancy. If you are, or might be, pregnant, you cannot get an MRI as part of this research.

After a researcher talks about the checklist with you, and if it is safe for you to go in the MRI scanner, we will ask you to do these things to get ready:

* Take off anything that could be made out of metal or have metal pieces such as: jewelry, watches, belts, hair holders, and eyeglasses.
* Take everything out of your pockets such as: keys, wallets, money, and credit cards.
* Take off your shoes.

You might also be asked to:

* Change into a hospital gown, “scrubs,” or other clothes that are best for being in the scanner. Some clothes have metal pieces in them that may heat up in the MRI scanner.
* Take off eyeshadow or other makeup. Some makeup can have tiny metal pieces in it.

A researcher will show you a secure place to store your things until the MRI scan is over.

* **IN THE MRI SCANNER**
When you go into the MRI scanner, you will lie down on a table that will slide into a tube or tunnel that is a little bigger than your body. You will be asked to stay as still as possible while you are in the MRI scanner. You will be able to hear and talk to the researchers while you are in the MRI scanner. Some people feel nervous or afraid when they are in small spaces. If you think you will be nervous or afraid, please tell the researchers before you go in the MRI scanner. The MRI scanner also makes loud noises when it is taking pictures. The researchers will give you ear protection so that it does not sound as loud. If you do not like the way you feel or are uncomfortable when you are in the MRI scanner, please tell the researchers. If you want to stop, you can at any time for any reason.

If other devices are being used that are not part of the MRI scanner, such as buttons to press or ways to monitor your heart beat, there is a very small chance that they might heat up while the MRI scanner is taking pictures. If you feel anything heating up or burning, please ask the researchers to stop the MRI scanner and let them know what you feel.

* **OTHER INFORMATION**
The MRI scan you will get as part of this research is not meant to find health problems. This MRI scan cannot be used instead of a medical examination by a qualified healthcare provider. If you think that you might be sick or injured, you should not use this MRI scan as a way to determine whether or not you are well.

The researchers for this project are not trained to make any medical diagnosis, and the MRI scans done in this research are not designed to find medical problems. The researchers and Brown University are not responsible for finding any abnormalities in your MRI scans. However, sometimes, a researcher may notice an MRI image that seems abnormal. If this happens, the researcher will let you know and recommend that you tell your primary care doctor. Only you and your doctor can decide whether or not you should have additional medical tests or treatment. The researchers and Brown University are not responsible for any medical attention that you decide to get based on the MRI images from this research. If you request it, the researchers will give MRI images to your doctor. However, because the MRI images were taken for research and not for medical purposes, they should not be used for medical decisions.

* **CONSENT TO PARTICIPATE**

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

 Participant's Signature and Date / PRINTED NAME