Consent Document for Enrolling
Adult Participants in a Research Study
at the
Georgia State University / Georgia Institute of Technology
CENTER FOR ADVANCED BRAIN IMAGING
831 Marietta Street, Atlanta, GA 30318

Project Title: GSU/GT Center for Advanced Brain Imaging Data Repository hosted by Collaborative Informatics and Neuroimaging Suite
Primary Investigator: Dr. Vince Calhoun
Repository Guardian: Dr. Nikki Arrington
Telephone: 404-385-8628

Introduction:
The Georgia State University/Georgia Tech Center for Advanced Brain Imaging (CABI) is a research imaging facility that allows us to study the structure and function of the human brain using magnetic resonance imaging (MRI). You are being asked to participate in this database repository because you are having or have had a brain scan done and data collected that could be beneficial for future research and in understanding the brain.

Key Information:
What Am I Being Asked To Do?
You are being asked for your permission to store the MRI brain scan images collected as part of your participation in a research study at CABI. This page will give you key information to help you decide if you would like to have your data stored and shared for future research. Your participation is voluntary. As you read, please feel free to ask any questions you may have about the research.

What Is This Repository For and What Am I Providing Permission For?
The purpose of this repository is to store imaging data that has been collected at CABI and shared with other researchers for future study. You are being asked to provide your permission for us to store your coded data for future unspecified research.

Are There Any Risks or Discomforts I Might Experience by Providing Permission?
Common risks of contributing data to a repository include the risk of a data breach where individual information could be exposed.

What Are the Reasons You Might Want to Volunteer For This Study?
You are not likely to benefit in any way from contributing your data to the repository. However, your data may assist future researchers in understanding how the brain works.

IRB NUMBER: H21617
IRB APPROVAL DATE: 06/02/2021
Do You Have to Take Part in This Study?
It is fully your decision if you wish to share your data or not. If you choose not to share your data, or provide your permission and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. Contributing your data to the repository is completely voluntary.

Purpose:
We would like to request your permission to store the imaging data that was or will be collected from you during a research study you agreed to participate in at CABI. We would like to store this data in the MRI Data Repository for future research. The stored data will include any structural MRI data (i.e., scans that provide information about the anatomy of your brain), functional MRI data (i.e., scans that provide information about the activity of your brain when you are resting), and/or neurochemical data (i.e., magnetic resonance spectroscopy) collected during your visit. In addition, health and demographic information from your Health Screening Form and MRI Screening Form will be collected. All information will be coded with a unique number. Any information that can identify you will be kept separate from the other data collected. Storage and sharing of data will be done in a way that protects your confidentiality and privacy.

Exclusion/Inclusion Criteria:
Only those who have had imaging data collected as part of their participation in a research study at CABI will be included in MRI Data Repository.

Procedures:
Your participation in the data repository will require no additional time or effort. Participation is voluntary, and you may choose not to participate. It will not affect your ability to participate in the primary study. All of the information and data we collect from you will be coded with a unique research subject identifier (URSI) number rather than by your name. This is to protect your privacy. URSI coded data will be stored indefinitely and for undefined future research. Data that is shared with other researchers will be de-identified before they receive it. Your birth year will be used in place of your birthdate. Researchers receiving data will not be able to identify you or that you participated in the original study. You have the right to withdraw your permission to share your data for research purposes at any time. To do so, please contact the repository guardian, Dr. Nikki Arrington at (404) 385-8628 or carrington3@gsu.edu.

Risks or Discomforts:
Risks associated with allowing your data to be stored in the data repository include a possible data breach where individual information is exposed, exposing participating in particularly sensitive studies (e.g. HIV or substance use study), and exposure of other personal information.

The MRI done as part of your participation in the primary study is for research purposes only. The MRI scan that is/was done is designed to answer research questions, not to
medically examine your brain. The MRI scan is not a substitute for one a physician would order. It may not show problems that would be picked up by a medical MRI scan. None of the researchers are medically qualified radiologists. However, if we see something unusual in your scan, your scan may be referred to a radiologist and you may be informed by the research group if follow up with your physician is suggested. Any follow-up evaluation or treatment that you seek will be at your own expense. Even if your physician rules out any problems, you may be unnecessarily worried if a problem is suspected.

**Benefits:**
You will not directly benefit from contributing your data to the repository. However, research done with information from the data repository could lead to improved diagnostic and treatment interventions for illnesses and brain disorders. If published, results will not include your name or other identifying information. If the institutions and/or the investigators develop products or services based on the results of the research using your data, there are no plans to provide you financial compensation.

**Alternatives**
The alternative to taking part in this study is to not take part in the study.

**Compensation to You:**
You will not be compensated for allowing your data to be stored in the repository or shared with other researchers.

**Voluntary Participation and Withdrawal**
You do not have to be in this study. If you decide to share your data and change your mind, you have the right to remove your permission for us to store your data. You may refuse to share your data or may change your mind at any time.

**Storing and Sharing and Future Use of Your Information:**
By signing below, you consent for your coded information/data to be stored by the research team and to have your de-identified data shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data before it is shared with other researchers. Future researchers will not have a way to identify you.

**Confidentiality:**
The following procedures will be followed to keep your personal information confidential in this study: We will comply with any applicable laws and regulations regarding confidentiality. We will take measures to protect your privacy and the security of all your personal information. Your name and other identifying information will be maintained in locked files and/or restricted databases, available only to authorized members of the research team for the duration of the repository. All research data, including MRI brain scans and information collected from the MRI and Health Screening Forms, will be stored...
separate from identifiable information using the assigned URSI. URSI coded
data will be kept on password protected computers, stored securely in restricted
and protected databases according to CABI information security policies. Your
information will be kept indefinitely (forever) at CABI in a confidential manner
so that you may continue to have access to your MRI information. Data from
this repository that does not contain any identifiers may be presented at
meetings, published in journals/books, used in classrooms for training/teaching
purposes, and may be used and shared with other researchers for future research
purposes, which includes scientists at other universities and institutions.
However, your name and other identifying information will not be used in any
published reports about this study.

The following people and entities will have access to the information you provide:

- Vince Calhoun and the approved research team
- The Georgia State University (GSU) Institutional Review Board (IRB)
- Office for Human Research Protection (OHRP)

Costs to You:
There are no costs to you, other than your time, for sharing your data.

Questions about the Study:
Contact Dr. Nikki Arrington at 404-385-8628 (email: carrington3@gsu.edu) if you:

- Have questions about the study or your part in it
- Have questions, concerns, or complaints about the study
- Think you have been harmed by the study

The IRB at Georgia State University reviews all research that involves human
participants. You can contact the IRB if you would like to speak to someone who is not
involved directly with the study. You can contact the IRB for questions, concerns,
problems, information, input, or questions about your rights as a research participant.
Contact the IRB at 404-413-3500 or irb@gsu.edu.

Participant Rights:

- Your participation is voluntary. You do not have to allow your data to be shared if
  you don't want it to be.
- You have the right to change your mind and withdraw your data from the
  repository at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about your data being
  stored or shared will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.
If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to volunteer to have your data stored in the MRI Data Repository.

Participant Name (printed)

Participant Signature  Date / Time

Person Obtaining Consent (printed)

Signature of Person Obtaining Consent  Date