**Study Title:** [Insert study name]

**Principal Investigator:** [Insert the name and title of principal investigator]

[Department, address city, state, zip, phone number, e-mail address]

**Faculty Advisor:** [Insert name and title of faculty advisor. Delete if not applicable]

**Other Investigator(s):** [Insert the names and titles of any other investigators. Delete if not applicable]

**Sponsor(s):** [Insert the name(s) of the Sponsor(s). Delete if not applicable]

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**Purpose of this Study**

The purpose of the study is to [Explain the purpose of your research and why it’s important to do the research.]

**Summary**

[Provide a concise and focused presentation of the key information that will assist the prospective participant to understand the reasons ***why they might or might not want to participate in the research***.]

**Procedures**

[Describe the research procedures in layman’s terms. Provide a detailed description of any procedures expected to be performed on or by the participants.]

[If applicable, describe any use of video and/or audio recording that may occur during the study. Also explain how you intend to use these recordings and who will be given access to the recordings.]

[Insert the expected duration of participation in the study. Indicate the location where research will be performed so that participants may estimate travel time.]

**Participant Requirements**

[List the requirements for inclusion of participants in the study. Include age requirement.]

You may not participate in this study if:

* You know or have any suspicion that you may have a metallic object in your body. This includes things such as a cardiac pacemaker, cochlear implant, metal IUD (hormonal IUD’s made of plastic are fine), neurostimulator, aneurysm clips, non-removable body piercing, history of shrapnel or metal fragments in the eye.
* You are pregnant. If there is a possibility that you are pregnant you will be given a pregnancy test at no cost. If you are pregnant you will not be able to participate in the study.
* You have a history of claustrophobia.
* You have permanent metal braces or a molar retainer
* You weigh more than 300 pounds.

[List any additional exclusion criteria for the study such as medical conditions, age, etc.]

**Risks**

The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life or during [Insert routine activity that is the same or similar to the study tasks. If study has specific potential risks beyond “daily life”, include a description of the specific risks and discomforts that may be associated with participation in the study]]

There is a potential risk of the powerful magnetic field of the magnet attracting ferromagnetic / metallic objects towards the magnet. For this reason you will be screened for metallic objects in your possession or in your body before entering the room with the magnet. All metallic items will be collected and placed in a locker outside the room. You must tell the technologist if you suspect you have any metal in your body.

[Include a description of the any additional specific risks and discomforts associated with participation in the study]

**Benefits**

There may be no personal benefit from your participation in the study but the knowledge received may be of value to humanity. [Or delete the previous statement and insert description of benefits applicable to the study]

**Incidental Findings**

There is a remote possibility that the MRI will indicate something unusual or different about your brain that has nothing to do with this study. The MRI is being done to answer research questions, not diagnose brain disorders. In the unlikely event we detect significant abnormalities in the scans of your brain, the technologist will ask a qualified radiologist to review the scans. There will be no charge to you for this review. We will contact you with the radiologist’s findings. You will be responsible for following up with your physician if anything is identified.

**Compensation & Costs**

[If applicable, list any compensation provided. Please specify whether participants will be paid for their participation. Indicate what partial payment will be given if participant does not complete the study. ] [If applicable, indicate that participants may be asked for their social security numbers if the payment is or exceeds $250.]

There will be no cost to you if you participate in this study. [If applicable, delete the previous statement and list any costs associated with participation in the study]

**Medical Treatment Costs**

Carnegie Mellon University is not offering financial compensation, payment for the costs of medical treatment, or emergency care should you be injured as a result of participating in this study.

**Future Use of Information and/or Bio-Specimens** [Describe any plan for future use of the data, e.g., to archive, store, or share it. The sharing should be described in terms of the level of identifiability of the data. If applicable, provide a statement that explains whether or not you will or might use the participant’s data (information or bio-specimens) in a future research study.

In the future, once we have removed all identifiable information from your data (information or bio-specimens), we may use the data for our future research studies, or we may distribute the data to other investigators for their research studies. We would do this without getting informed consent from you (or your legally authorized representative).

**Confidentiality**

By participating in the study, you understand and agree that Carnegie Mellon may be required to disclose your consent form, data and other personally identifiable information as required by law, regulation, subpoena or court order. Otherwise, your confidentiality will be maintained in the following manner:

Your data and consent form will be kept separate. Your research data will be stored in a secure location on Carnegie Mellon property. Sharing of data with other researchers will only be done in such a manner that you will not be identified. By participating, you understand and agree that the data and information gathered during this study may be used by Carnegie Mellon and published and/or disclosed by Carnegie Mellon to others outside of Carnegie Mellon. However, your name, address, contact information and other direct personal identifiers will not be mentioned in any such publication or dissemination of the research data and/or results by Carnegie Mellon. Note that per regulation all research data must be kept for a minimum of 3 years.

[Indicate here whether annotation services will be used. Specify whether the annotator will be bound by a confidentiality agreement or if annotation will be crowdsourced.]

[Describe any other positive measures taken to protect the participant’s privacy and the confidentiality of research data (i.e. recording data by assigned numbers, not participant names, encryptions, etc.]

**SUGGESTED LANGUAGE**: *The researchers will take the following steps to protect participants’ identities during this study: (1) Each participant will be assigned a number; (2) The researchers will record any data collected during the study by number, not by name; (3) Any original recordings or data files will be stored in a secured location accessed only by authorized researchers*. **Please note that this is suggested language only. You should revise this language as necessary to accurately describe all the procedures you will use to protect participants’ confidentiality.**]

[If applicable, describe how the participant’s confidentiality will be maintained with regard to the use of any video and/or audio recordings]

[If the study is sponsored indicate that the sponsor may have access to research records.]

[If NIH has granted a certificate of confidentiality place the suggested consent form language from NIH here. See [Certificate of Confidentiality guidance](https://www.cmu.edu/research-compliance/human-subjects-research/nih-funded-studies/certificate.html)]

**Optional Permission**

[If you are not recording any audio or video or if you have no plans to publicly disclose these recordings, delete this entire section.]

I understand that the researchers may want to use a short portion of any video or audio recording [include only the type to be done in this study] for illustrative reasons in presentations of this work for scientific or educational purposes. I give my permission to do so provided that my name and face will not appear.

[Be sure the language covers all your intended uses. For example, if you intend to post clips on the internet or use the recordings in some other manner, you will need to change the language to reflect your intentions.]

Please initial here: \_\_\_\_\_\_\_YES \_\_\_\_\_\_\_\_NO

**Rights**

Your participation is voluntary. You are free to stop your participation at any point. Refusal to participate or withdrawal of your consent or discontinued participation in the study will not result in any penalty or loss of benefits or rights to which you might otherwise be entitled. The Principal Investigator may at his/her discretion remove you from the study for any of a number of reasons. In such an event, you will not suffer any penalty or loss of benefits or rights which you might otherwise be entitled.

**Right to Ask Questions & Contact Information**

If you have any questions about this study, you should feel free to ask them now. If you have questions later, desire additional information, or wish to withdraw your participation please contact the Principal Investigator by mail, phone or e-mail in accordance with the contact information listed on the first page of this consent.

If you have questions pertaining to your rights as a research participant; or to report objections to this study, you should contact the Research Regulatory Compliance Office at Carnegie Mellon University. Email: [irb-review@andrew.cmu.edu](mailto:irb-review@andrew.cmu.edu) Phone: 412-268-1901 or 412-268-5460.

**Conflict of Interest**

[In this section, please disclose any conflict of interests the researchers may have with this research study, including but not limited to, financial conflicts of interests. If there are no conflicts of interest, please delete this section]

**Voluntary Consent**

[Three options are available for this section: Competent Adult; Minors; Adults lacking the capacity to consent.  **Please include only those that apply and delete the others**.]

By signing below, you agree that the above information has been explained to you and all your current questions have been answered. You understand that you may ask questions about any aspect of this research study during the course of the study and in the future. By signing this form, you agree to participate in this research study. A copy of the consent form will be given to you.

PRINT PARTICIPANT’S NAME

PARTICIPANT SIGNATURE DATE

I certify that I have explained the nature and purpose of this research study to the above individual and I have discussed the potential benefits and possible risks of participation in the study. Any questions the individual has about this study have been answered and any future questions will be answered as they arise.

SIGNATURE OF PERSON OBTAINING CONSENT DATE

[MINORS: In the event the protocol includes minors, the language below must be included. Minors (individuals under the age of 18) are not legally able to consent to research. Consent must be provided by the participant’s parent or legal guardian. If a child is of an age and mental ability that s/he is capable of understanding the concept of research and the research activity, the child’s assent must be sought and documented in addition to the parent’s.]

By signing below, you agree that the above information has been explained to you and all your current questions have been answered. You understand that you may ask questions about any aspect of this research study during the course of the study and in the future. By signing this form, you agree that your child may participate in this research study. A copy of the consent form will be given to you.

PRINT PARENT’S NAME

PARENT SIGNATURE DATE

PRINT THE CHILD’S NAME

Minor’s Assent

This research has been explained to me and I agree to participate.

MINOR’S SIGNATURE DATE

I certify that I have explained the nature and purpose of this research study to the above individual and I have discussed the potential benefits and possible risks of participation in the study. Any questions the individual has about this study have been answered and any future questions will be answered as they arise.

SIGNATURE OF PERSON OBTAINING CONSENT DATE

[ADULTS LACKING THE CAPACITY TO CONSENT: In some cases consent cannot be obtained from an adult participant because the research participant lacks the ability to read and comprehend the consent form (for example, the participant may have diminished cognitive abilities due to Alzheimer’s Disease). In such cases, the researchers should seek the participant’s assent to participate in the study and the consent of the person legally responsible for the participant. If the participant does not wish to participate in the study, he/she cannot be enrolled in the study unless the person legally responsible

for the participant determines that it is in the participant’s best interest.]

**Adult Assent**

If you cannot give legal consent to take part in this study because you may have trouble reading or understanding this consent form, then the researcher will ask for your assent. Assent is your agreement to be in the study. The researcher will explain the study to you in words that you can understand. You should ask questions about anything you don’t understand. Then you should decide if you want to be in the research study. If you want to participate, you or someone who can sign a legal document for you must also give their permission and sign this form before you take part.

By signing below, you agree to participate in this study:

PRINT PARTICIPANT’S NAME

PARTICIPANT’S SIGNATURE DATE

**Consent of Guardian / Representative**

### If you have authority to consent on behalf of the above named participant, please print your name

### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and indicate your relationship to the participant:

\_\_\_\_\_ The participant’s legal guardian

\_\_\_\_\_ A surrogate

\_\_\_\_\_ A durable power of attorney

\_\_\_\_\_ A proxy

\_\_\_\_\_ Other, please explain:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

By signing below, you warrant that you have the authority to make decisions on behalf of the participant. You agree that the above information has been explained to you and all your current questions have been answered. You understand that you may ask questions about any aspect of this research study during the course of the study and in the future. By signing below, you consent to the participant’s involvement in this study.

SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE DATE

I certify that I have explained the nature and purpose of this research study to the above individual and I have discussed the potential benefits and possible risks of participation in the study. Any questions the individual has about this study have been answered and any future questions will be answered as they arise.

SIGNATURE OF PERSON OBTAINING CONSENT DATE