**UNIVERSITY OF NORTH CAROLINA AT GREENSBORO**

THIS IS A TEMPLATE FOR OBTAINING INFORMED CONSENT FOR PARTICIPATION IN RESEARCH. IT MUST BE ADAPTED TO INCLUDE ALL OF THE INFORMATION REQUIRED (**RED TEXT INDICATES REQUIRED LANGUAGE**) FOR INFORMED CONSENT. IF AN ITEM IS NOT APPROPRIATE FOR THE STUDY, PLEASE DELETE IT FROM THE FORM. SEE THE ORI WEBPAGE FOR OTHER EXAMPLES/TEMPLATES.

PLEASE NOTE THAT ALTERATIONS TO TEMPLATE LANGUAGE ARE ALLOWED WITH JUSTIFICATION. PLEASE MAKE SURE FONT SIZE IS CONSISTENT AND IN BLACK.

**CONSENT TO ACT AS A HUMAN PARTICIPANT**

**Requited fMRI / MRI language is in green**

Project Title:

Principal Investigator and Faculty Advisor (if applicable):

Participant's Name:

**What are some general things you should know about research studies?**
You are being asked to take part in a research study.  Your participation in the study is voluntary. You may choose not to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future.   There may not be any direct benefit to you for being in the research study. There also may be risks to being in research studies. If you choose not to be in the study or leave the study before it is done, it will not affect your relationship with the researcher or the University of North Carolina at Greensboro.
Details about this study are discussed in this consent form.  It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form.  If you have any questions about this study at any time, you should ask the researchers named in this consent form. Their contact information is below.

**What is the study about?**

This is a research project. Your participation is voluntary. This section should include a statement that the study involves research and the purpose of the study.

**Why are you asking me?**

The reason for selecting the participant; inclusion/exclusion criteria

MRI uses a very strong magnetic fields and powerful radio waves. While MRI an MRI exam is safe for most people, there are a number of instances when it is unsafe (even potentially fatal) for someone to be in or around a MRI scanner. In order to make sure the MRI procedure will be safe for you, you will be asked to fill out a screening form before starting the study. It is important that you tell the researchers in this study:

o if you have a heart pacemaker

o if you have metal in your head (not including dental work)

o if you have metal in your spine or heart

o if there is the possibility of metal in your eyes,

o if you have any implanted medical device in your body,

o if you have an implant in your body held in place with a magnet,

o if you have had surgery in the last 6 weeks,

o if you weigh more than 450 pounds,

o if you are pregnant or there is the possibility that you are pregnant.

**What will you ask me to do if I agree to be in the study?**

The activities involved and identification of any procedures which are experimental, the expected duration (time) of the participant’s participation, and any anticipated follow-up should be discussed. Any procedure which is likely to cause stress, pain (physical, psychological or emotional), or any other unpleasant reaction should also be described (but risks will need to be placed in risks section below), and a number with a contact person answer questions so that the person understands fully to what they are consenting.

Before your MRI exam is scheduled you will be asked to answer a series of questions about your medical history to determine if an MRI exam is safe for you. We are interested in knowing if you have any metal inside your body that could results in injury during the MRI exam. You will also be asked your height, weight, sex, and birthdate. After it has been determined that it is safe for you to have an MRI exam, your MRI exam will be done at the Joint School of Nanoscience and Nanotechnology in Greensboro, NC.

On the day of your scheduled MRI exam, you will be asked to answer the same questions again to verify that nothing has changed and that it is still safe for you to have an MRI exam. You will be in the MRI scanner for about 60 minutes.

For your safety, you will be monitored the entire time you are in the scanner. The study team will be able to talk to you and hear you talk during the exam through an intercom. You will also be given a safety-ball to squeeze with your hand if you want to stop the exam at any time for any reason.

**\*\*FOR RESEARCH INVOLVING BIOSPECIMENS ONLY. DO NOT INCLUDE THIS SECTION IF YOU ARE NOT USING BIOSPECIMENS:**

**How will my biospecimens be used?**

Please include a brief description of how biospecimens will be used and where they will be stored. If they will be sent to an outside lab for analysis, please state and include whether they will be sent in an identifiable or de-identified state.

Please include the following elements WHEN APPROPRIATE for your study:

* A statement that the participant’s biospecimens (even if identifiers are removed) may be used for commercial profit an whether the subject will or will not shar in the commercial profit
* A statement regarding whether clinically relevant research results, including individual research results will be disclosed to subjects an if so, under what conditions
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (ie sequencing of human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

**Is there any audio/video recording?**

This section should describe any plans to use audio/video recording if it is applicable to the project proposed. It should include the statement “Because your voice will be potentially identifiable by anyone who hears the tape, your confidentiality for things you say on the tape cannot be guaranteed although the researcher will try to limit access to the tape as described below.”

**What are the risks to me?**

Please include the following statement: “The Institutional Review Board at the University of North Carolina at Greensboro has determined that participation in this study poses minimal risk to participants.” If there are minimal risks or more than minimal risks, describe the risks. Research involving more than minimal risk must also include an explanation as to whether compensation, medical, psychological or other types of treatments are available if injury or a stressful situation occurs. If there is only low to minimal risk, please simply state “minimal risk”

Please include a referral in this section if your study involves questions that ask about mood, depression or anxiety.

The Institutional Review Board at the University of North Carolina at Greensboro has determined that participation in this study poses minimal risk to participants. MRI scanners have been in clinical use for about 20 years. When the MRI is used properly, there are no known risks to having an MRI scan for most people. Unlike X-rays, CT scans, and nuclear medicine studies, the MRI machine does not use X-rays or other forms of ionizing radiation. Instead, the MRI scanner uses strong magnetic fields and radio waves to measure your brain activity when you lay on a bed in a tube.

**Metal objects:** Metal objects within or on your body and clothing can cause harm to you, in addition to distorting the quality of the MRI images. Such things as keys, watches, and credit cards will be kept safely away from the machine. We will ask you to take off all removable metal (e.g. jewelry, piercings, etc.). People with devices or objects inside their body that are affected by strong magnetic fields (i.e. metallic foreign bodies inside your head or in your eyes, incompatible medical implants, pacemakers, brain stimulators, blood vessel clips, etc.) will not be allowed to participate under any circumstances. Knowingly participating in this study with these types of metallic implants can lead to serious injury or death. Although metal objects sensitive to strong magnetic fields are not allowed in the MRI scanner, there are many metal objects that are not sensitive to strong magnetic fields, such as dental work, pins or screws used during surgery, and even some tattoos contain metal. People with these types of metal objects may safely participate in this study. You will go through an extensive screening process to determine if the MRI scanner is safe for you before allowing have your MRI exam

**Burn risks**: In extremely rare cases, metal in the body (e.g., in tattoos) exposed to the powerful radio waves used in MRI may heat up. This heating occurs gradually but if it goes unreported during the MRI exam it could lead to burns. Such burns are easily prevented by reporting any heating sensations that you have to the technologists immediately. For your safety, you will be monitored the entire time you are in the scanner. The study team will be able to talk to you and hear you talk during the exam through an intercom. You will also be given a ball to squeeze with your hand if you want to stop the exam immediately and for any reason.

**Fear of small places:** MRI machines require you to enter a tube about 2 feet in diameter and place your head in small helmet. For people with a fear of small spaces this can cause anxiety. If you experience anxiety during your MRI exam please let the technologist know. If you decide that you cannot complete the scan, you will be removed immediately from the scanner, and released from the study.

**Hearing loss:** MRI scanners when taking a picture are very loud. You will be required to wear earplugs during the exam. When the earplugs are used properly, the noise from the MRI scanner is as load as a garbage disposal or food blender. If the earplugs are not inserted into the ear canal then temporary hearing loss is possible. If at anytime the noise from the MRI machine is too loud inform the technologist.

**Muscle twitching and tingling:**  MRI machines turn magnetic fields on and off very quickly to make an image. In rare cases, this may cause your muscles to twitch and tingle. The muscle twitching and tingling are temporary and will stop as soon as the scanner stops. In some rare cases, some individuals find the muscle twitching and tingling to be uncomfortable and cannot continue with the MRI exam. If this happens to you let us know and you will be released from the study.

**Other miscellaneous risks:**  There are other short-term effects that have been reported in very rare cases during the MRI exam. These effects range from dizziness, to taste sensations, to light flashes during the MRI exam. These effects are temporary and occur as you move in and out of the MRI machine. In most cases, these effects go away very quickly. If these sensations persist and you are unable to continue with the MRI exam, inform the researchers and you will be removed from the MRI exam and released from the study.

* The MRI images completed at our facility are part of a research study and are not for clinical diagnostic purposes. The MRI images in this study will not be reviewed by a physician. If you would like to review these images with your physician, we will give you a free copy of your images on a CD.
* In the case that we see a substantial deviation from normal anatomy we will notify you, provide you with a free copy of your data, and suggest that you contact your physician for follow up. The research team cannot diagnose conditions.

**Pregnancy**: It is unclear at this time whether strong magnets are a risk to unborn fetuses. Due to the unknown risk and potential harm to an unborn fetus from any MRI scan, pregnant women will be excluded. All women will be asked before entering the scanner if they are pregnant.

The MRI images completed as part of this study are not for clinical diagnostic purposes. The MRI images in this study will not be reviewed by a physician. If you would like to review these images with your physician, we will give you a copy of your images on a CD.

Would you be like a copy of your images? Yes □ No □

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you have questions, want more information or have suggestions, please contact (name of principal investigator AND faculty advisor, if applicable) who may be reached at (333) 333-3333 (you can also include your email address if you like).

If you have any concerns about your rights, how you are being treated, concerns or complaints about this project or benefits or risks associated with being in this study please contact the Office of Research Integrity at UNCG toll-free at (855)-251-2351.

**Are there any benefits to society as a result of me taking part in this research?**

Describe any benefits to society that may result from this study. Be sure that your language does not guarantee any benefits (use the word “may”).

**Are there any benefits to *me* for taking part in this research study?**

Participants should be informed about direct or indirect potential benefits to them or others or the absence of benefits. Be sure that your language does not guarantee any benefits (use the word “may”). Elements related to payment (remuneration) are NOT considered “benefits” to a participant and should be discussed within the Costs/Payments section. If there are no direct benefits, indicate, “There are no direct benefits to participants in this study.”

**Will I get paid for being in the study? Will it cost me anything?**

Costs and Payments to the Participant should be addressed explicitly, including a statement that payments will not be given if that is the case. Describe how payments will be made if the participant elects to discontinue participation during the study. If there are no costs or payments involved you may state, “There are no costs to you or payments made for participating in this study.”

**How will you keep my information confidential?**

Describe how information will be kept confidential. For example: stored in a locked file cabinet, password protection, encryption, not identifying participants by name when data are disseminated, anonymous data collection procedures, and what the disposition of the data will be and how long it will be kept. Include a statement that reads "all information obtained in this study is strictly confidential unless disclosure is required by law." If applicable, the researcher must add a description of any legal duty to report abuse that might supersede these confidentiality promises.

**Will my de-identified data be used in future studies? – THIS SECTION IS ONLY TO BE USED IF USING DATA IN FUTURE STUDIES**

If the PI plans to use the participant’s de-identified data data for future studies, please state: “Your de-identified data will be kept indefinitely and may be used for future research without your additional consent.”

If the PI does **NOT** plan to use the participant’s de-identified data data for future studies, please state: “Your data will be destroyed at \_\_\_\_\_\_\_\_\_\_(state when data will be destroyed). De-identified data will not be stored and will not be used in future research projects.

**For Internet Research, include this wording:** “**Absolute confidentiality of data provided through the Internet cannot be guaranteed due to the limited protections of Internet access.** **Please be sure to close your browser when finished so no one will be able to see what you have been doing."Alternatively, add security statement from commercial survey tool used for the study.**

**What if I want to leave the study?**

“You have the right to refuse to participate or to withdraw at any time, without penalty. If you do withdraw, it will not affect you in any way. If you choose to withdraw, you may request that any of your data which has been collected be destroyed unless it is in a de-identifiable state.”

**What about new information/changes in the study?**

“If significant new information relating to the study becomes available which may relate to your willingness to continue to participate, this information will be provided to you.”

**Voluntary Consent by Participant:**

By signing this consent form/completing this survey/activity (used for an IRB-approved waiver of signature) you are agreeing that you read, or it has been read to you, and you fully understand the contents of this document and are openly willing consent to take part in this study. All of your questions concerning this study have been answered. By signing this form, you are agreeing that you are 18 years of age or older and are agreeing to participate, or have the individual specified above as a participant participate, in this study described to you by      .

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_