INSTRUCTIONS FOR USE OF THE MODEL CONSENT FORM

- Use the language of this model consent form, making adjustments for each individual study where indicated.
- A detailed explanation about what is required for each section appears in small blue type and is italicized. Use this for your information, but do not reproduce this language in your consent form.
- Standard language appears in black. It should be included in your form; however, it may need to be modified to the specifics of your study.
- Areas printed in green are for you to adapt to fit your study and then be included in the form.
- Be sure to check the General Guidelines that are posted below the model.
- Once a consent form is created using this model, a reviewer will determine if the uniqueness of your study requires revision of the form.
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If you decide to participate, you will <enter a detailed description of the participant's activities>.

- A detailed description and explanation of the procedures that will be performed on the subject, e.g. filling out questionnaires, being interviewed, being audio or videotaped, engaging in role playing, performing computerized experiments, etc.
- A full explanation of all responsibilities and expectations of the subject. Be sure to communicate the following:
  - All of the different people with whom the subject will interact
  - Where the research will be done.
  - When the research will be done.
  - How often the procedures will be performed.
  - How much of the subject's time will be involved, total, and in each session or task
  - Compensation information if relevant, including a schedule of payments

protected computers. If you are using a key (code sheet) to identify the research participant or the like, indicate that the key will be stored separately from the data to protect privacy.> Your name and other facts that might point to you will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. You will not be identified personally.

If you are using a key (code sheet) to identify the research participant, please indicate when the key will be destroyed.
If you are using audio or visual media, please indicate how the media will be stored and kept private. Specify the length of time the media will be stored and when it will be destroyed.
If focus groups are used, the limits of confidentiality must be discussed. Participants should be asked not to reveal what was discussed in the group, but should also be warned that researchers do not have complete control of the confidentiality of the data.
If internet participants are recruited, the limits of confidentiality must also be discussed.
If the FDA is not relevant or you do not have a sponsor, those do not need to be included.

VII. Contact Persons:

Contact <name of PI or faculty advisor and student PI> at <telephone number and email address> if you have questions, concerns, or complaints about this study. You can also call if you think you have been harmed by the study. Call the chair of the Middle Georgia State College IRB <insert current chair's phone number here> if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, offer input, obtain information, or suggestions about the study. You can also call the IRB chair if you have questions or q

sought. In some cases, further adjustment is needed because both the parent and the child are potential participants; the language of the consent form must reflect this clearly. ***If the proposal involves minor children e.g., dual enrollment students, please contact the MGSC IRB chair for additional guidelines and child's assent form***

2. When relevant, consent forms should make clear what the participant is doing for the purposes of research (what you will collect data on) and what he/she is doing for other purposes (receiving routine instruction, routine medical care, etc). This applies to studies that take place in the context of normal, ongoing activities that are not for research purposes. For example, if a researcher is studying the scores on weekly spelling tests that are given routinely whether the research is being conducted or not, the consent form must be clear that permission is being sought to use the test scores for the purposes of research. Permission is not being sought for the students to take the tests, since they will do this anyway in the course of instruction. However, if the researcher introduces an intervention that is NOT part of routine practices, the entire process is research and consent must be provided for all aspects of the procedure.

3. Please Proof Read

Look for the following:

- Spelling, Typographical, and Grammatical Errors

Consent forms should never be written in 1st person. (DO NOT Use "I am being asked to be in a research study...."). Use the 2nd person when the individual reading the consent form is the study participant.

Be sure the document consistently refers to the potential participant as "you."

Include a version date and page numbers
Use at least a 12 point font.
The form needs to have one inch margins on all sides.
Be sure to leave room on the bottom of each page for the approval stamp.

Language that Must be Included in Certain Studies:

1. For Higher Risk Studies Only

Add a numbered section before the Contact section as follows:

XX. Middle Georgia State College Disclaimer:
If you have any question about this study, or believe you have suffered any injury because of participation in the study, you may contact [Prin

It may not be safe for you to have an MRI scan if you have certain metals in your body or have certain medical conditions. If you have any of the following, you will be excluded from this study for your own safety: Cardiac pacemaker; hearing aid; any other implant metal in your body or eyes, including pins, screws, shrapnel, plates, braces on your teeth, or dentures; Parkinson's, Alzheimer's, or other dementia; sickle cell anemia; epilepsy; bipolar disorder; multiple sclerosis; or brain surgery.
If you have tattoos, you could experience some irritation and redness at those sites. Tattoos on the head, such as eye liner or other permanent makeup, may make it impossible to get clear and usable images. If you have tattoos or permanent makeup of any type, you should inform us immediately.
[Researchers should also state any other exclusionary and inclusion criteria in this section.]

Risks or Discomforts:
The following risks or discomforts may occur as a result of your participation in this study. The MRI room may be cold and you may become tired or bored from lying in the scanner. If you are cold, you may request a blanket. If you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine. The MRI scanning procedure requires that you be confined in a small partially enclosed space. Some individuals find this to be uncomfortable and may exhibit symptoms of claustrophobia including nervousness, sweating or other minor discomfort. The sound of the MRI scanner can be quite loud; you will be given special ear plugs to minimize the noise. In addition, the magnetism of the machine attracts certain metals;

information may keep you from obtaining health or life insurance, depending on the specifics of your scan. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found. If you need to talk to someone about your concerns about an abnormal finding, you will be referred to a counselor at your own expense.

MRI Pictures: