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.
- This model is updated regularly to conform to new Federal regulations or guidance. Before you submit a new protocol, be sure to check back for any changes in the consent requirements.
- Consent forms should be submitted in final form. There should be no instructions or general guidelines on the form and there should be no tracked changes.

Middle Georgia State University (MGA)

<Enter department or school name>

Informed Consent

Title: <Enter title of study>

Principal Investigator: <Include name of P.I. and other investigators as appropriate>

If this document is for a student project, enter the faculty advisor as PI and on a second line enter the student as Student P.I.

Sponsor: <If the study is funded, include the sponsor's name. If not, omit this line>

Are you 18 years of age or older? Yes No (If "No", you need a different form; please see the principal investigator)

I. Purpose:

You are invited to participate in a research study. The purpose of the study is to investigate <enter purpose>. You are invited to participate because you are <enter why they may meet the study inclusion criteria>. A total of approximately <enter number> participants will be recruited for this study. Participation will require <enter amount> of your time over <enter the span of time and specify dates if possible>.

At a minimum, this part of the consent form must include:

- *A statement that potential subjects are being asked to volunteer for a research study*
- *An explanation of why the subject is being asked to volunteer.*
- *A clear explanation of the purpose of the research.*
- *The expected duration of the subject's total participation, and*
- *The approximate number of patients to be enrolled in the study at MGA and elsewhere. (This is especially important when the number of subjects is material to the subject's decision to participate; e.g., small sample size might compromise confidentiality.)*

II. Procedures:

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*

III. Risks:

In this study, you will not have any more risks than you would in a normal day.

----OR ----

There is the possibility that participation in this study may cause you <name consequence>. <State what you will do to try to prevent this>. If you experience <name consequence and state the response that will be taken and who will pay for any treatment, if relevant>.

IV. Benefits:

Participation in this study may or may not benefit you personally. <If there is personal benefit, name it>. Overall, we hope to gain information about <specify the benefit to society>.

Sometimes, it may be necessary to inform subjects that there may be no benefit to the subject. Any benefits to the subject or others that can be expected should be described, but in a manner that is not coercive, enticing, or self-serving. Benefit to society is appropriate. Do not refer to financial compensation or grade compensation (extra credit) in this section (any remuneration should be in the procedures section).

V. Voluntary Participation and Withdrawal:

Participation in research is voluntary. You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop participating at any time. Whatever you decide, you will not lose any benefits to which you are otherwise entitled. (This paragraph can be adapted to better fit your study {i.e. if your study does not involve questions, don't include the sentence about skipping questions}. If you can, the benefits which the participant will not lose should be personalized to your study {i.e. grades, how you are treated in the workplace, medical treatment})

VI. Confidentiality:

We will keep your records private to the extent allowed by law. <Please specify PI and research team> will have access to the information you provide. Information may also be shared with those who make sure the study is done correctly (MGA Institutional Review Board, the Office for Human Research Protection (OHRP) <if your study is funded state the name of the funding source>, <if you are using FDA approved drugs or devices, the food and drug administration should be included>). We will use <indicate the code: a study

number, your initials, etc> rather than your name on study records. The information you provide will be stored <specify where and under what security provisions - e.g., locked cabinet, password- and firewall-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 University IRB <insert current chair's name and 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 concerns about your rights in this study.

VIII. Copy of Consent Form to Subject:

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below. (If the study involves recording this sentence will need to state, "If you are willing to volunteer for this research and be audio or video recorded {choose which applies}, please sign below.")

_____	_____
Participant	Date
_____	_____
Principal Investigator or Researcher Obtaining Consent	Date

GENERAL GUIDELINES:

1. Consent forms for parents or guardians of participants:
The consent form language of the document above should be modified. The title of the consent should be changed to "Parental Permission Form". Each time the word "you" or "your" appears in the model above, change it to read "your child" or "your child's." The signature line will need to state "Parent or Guardian". A line could be added for the parent to print the child's name, but the child will not sign the parental permission form. Use

common sense; there may be other places where changes need to be made for the consent form to clearly reflect that it is the parent's permission for the child's participation that is 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 MGA 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 signing the consent form is the study participant.
  - ✓ Be sure the document consistently refers to the potential participant as "you."
  - ✓ If consent will be obtained from someone other than the actual participant (e.g., a parent, next of kin, or legal guardian) the consent form should be written in the 3rd person (e.g., "Participants in this study will undergo the following tests and procedures.") This is especially true if the consent form sometimes will be given to the subject and sometimes to a parent or guardian. Avoid the following style: "If you (your child) agree/agrees to participate in this study you/he/she will have the following tests and procedures performed."

- Readability
  - ✓ The consent form must be written at the reading level of your least educated subject. When writing the consent form, aim for an 8th grade level. Half of all adult Americans read at or below the 8th grade level. Most word processors include utilities in the "Tools" menu to analyze the reading level of text.
  - ✓ Avoid using technical terms as much as possible. If you must use technical terms, explain what they mean in lay language.
  - ✓ Avoid long complex sentences. Write in short declarative sentences. Use simple words of fewer than three syllables whenever possible.
  - ✓ Do not use "You understand..." It implies the subject understands more than he/she may comprehend. It can be interpreted as suggestive and can constitute coercive influence over a subject.

- Format
  - ✓ Use Microsoft Word or other compatible software.
  - ✓ 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 University 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 [Principal Investigator] at [Phone Number]. <Information about what arrangements have been made to provide subjects with treatment should an injury occur or what referrals will be made needs to be provided in this section.> Middle Georgia State University [add other study sites as appropriate], however, has [have*] not set aside funds [to pay for this care or to compensate you*] if something should occur.

*[*Modify as appropriate. The suggested text is the minimum that must be included.]*

2. For Those Dealing With Protected Health Information or HIPAA

The information below should be modified to fit your study and be placed within the section entitled "Confidentiality" in the informed consent document:

We will keep your personal information private. Your privacy will be kept to the extent allowed by law.

The health information you give us will be used in this research study. We will remove all information that can identify you. We will share it with other people for this research study. If you decide you want to be in this study it means that you agree to let us use and share your personal health information for the reasons we have listed in this consent form.

While we are doing this research, the research team may use only the personal health information that you have given us: <your name, address, social security number, etc.>. The people and places that will be able to look at your personal health information are: <list the research team>. They will look at it so they can work on this research study. We may also share your health information with the Middle Georgia State University Institutional Review Board (IRB). Your personal health information may be shared by the people or places we have listed, but it will be shared in a way that does not fall under the protection of federal regulations that apply to the privacy of health information. This research may be shown to other researchers. This research may be published, but we will take steps to make sure that you cannot be identified.

If you sign this consent form you are letting us use your personal health information until the end of the study. You have the right to say that you do not want us to use your personal health information after we have collected it. If you decide you don't want us to use your information anymore you must write a letter asking us not to use your information. You will need to send the letter to the investigator

who received your completed questionnaires. This will be the only person who will be able to know which information is yours. We want to let you know that because the questionnaires do not have your name or address on them, we might not know which questionnaire is yours. If you don't want us to use your information anymore, we will stop using it, but any information that we have already used in the study will not be removed. <Only include the previous two sentences if the data will be completely de-identified and you will not be able to determine a participant's information.>
You may not be able to look at or get a copy of your health information that you gave us while we are doing the research; however you will be able to look at or get a copy at the end of the study.

3. For Studies Involving Concealment or Deception

*If your study involves **concealment** use the following wording in the procedures section of your consent documents:*
We will not tell you everything about the study in advance. When the study is over, we will tell you everything. At that time you can choose whether you want to let us use your information or not.

*If your study involves **deception** use the following language in the procedure section of your consent documents, if possible:*
During the study you may be led to believe some things that are not true. When the study is over, we will tell you everything. At that time you can choose whether you want to let us use your information or not.

4. For Imaging Studies Involving MRI Scans:

The following represents the minimal information that must be on informed consent forms for studies using MRIs. It may be modified or supplemented to fit the particular needs of your study, including any particular guidelines provided by your funding agency, as applicable. The MRI language is not meant to be a stand-alone consent form. This language should be inserted into the Model Consent Form only if a research study is using MRI scans. Depending on a your study's participants, the readability of this form may be too high - although some difficult words cannot be avoided, many of the complicated words can and should be simplified for participants who would have difficulty reading.

MRI Explanation/Procedures:
An MRI (or magnetic resonance imaging) scan is an imaging technique that uses magnetism, radio waves, and a computer to produce images of body structures. The MRI scanner is a tube surrounded by a giant circular magnet. You will be asked to lie still on a moveable bed that is inserted into a small tunnel inside the magnet. You will be asked to conduct certain activities or to listen to certain instructions/music and the MRI scan will produce the resulting images. The images produced by the MRI are detailed and can detect changes of structures within the body. For some procedures, contrast agents such as gadolinium may be used to increase the accuracy of the images.

MRI Exclusion/Inclusion Criteria:
You may experience nausea if you have certain conditions such as migraines, vertigo, anxiety, stress, fatigue, pregnancy, food poisoning, digestive disorders, fibromyalgia, concussion, brain injury, appendicitis, kidney or liver disorders, central nervous system disorders, brain tumors, some forms of

cancer, or other illnesses. If you are currently experiencing nausea for any reason, you should not have an MRI scan until your nausea has subsided.
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; therefore, people with these metals within their bodies (such as pacemakers, infusion pumps, aneurysm clips, metal prostheses, joints, rods, or plates) will be excluded from the study. The "metal" in dental fillings is less responsive to magnetism and is therefore allowed. The MRI technician will ask you if you have any metals within your body. **You will be expected to notify us of any metal in your body, other than dental fillings.** There are no other known side effects resulting from exposure to the MRI scan. If we do see something abnormal in your MRI scan, there is a risk that you may worry for no reason for a period of time until you can see a physician.
[If women of childbearing potential will be enrolled, and if there are no other known risks to them or their possible fetuses, the following statement is required:] Women of childbearing potential who are considering being in this study should especially note that the risks to fetuses of exposure to MRI are unknown.

Incidental Findings:
The MRI scan being done is designed to answer research questions, not examine your body medically. The researchers for this project are not trained to perform radiological diagnosis. This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. The researchers and Middle Georgia State University are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the researchers may notice a finding on a MRI scan that seems abnormal. When this occurs, a radiologist will be consulted as to whether the finding merits further investigation, in which case the researchers will contact you and inform you of the finding as soon as reasonably possible. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The researchers, the consulting radiologist, and Middle Georgia State University are not responsible for any delays in contacting you about any abnormal findings or any examination or treatment that you undertake, or fail to undertake, based upon these findings. No information generated in this study will become part

of a hospital record routinely. However, if the study detects an abnormality in your MRI scan, then this information may become part of the hospital record. If something abnormal is found, such 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:
Your MRI pictures are for research only and are not meant to evaluate your health (as they would be if they were part of a clinical, non-research visit to the doctor or hospital).
[If the Principal Investigator intends to provide copies of the images to the participant, then the following sentence should be included:]
However, you will be provided with a copy of the MRI pictures at no cost to you to keep and review as you see fit.

5. For Wavier of Documentation of Consent and Online Studies

With the waiver of documentation of consent, consent with all of the required elements of consent are still provided or read to the participant, but no signature is obtained. The same model consent form can be used to make the consent document or the consent script, but no signature lines will be on the form. The line above the consent form should also be modified to reflect what constitutes consent such as, "If you agree to participate in this research, please continue with the survey."
For most online studies, a waiver of documentation is appropriate because it would not be possible to obtain a signed consent form. The line above the signature lines should be changed to something that would be appropriate for the study such as "If you agree to participate in this research, please click the continue button." The form should state that the participant can print a copy of the form for his/her records instead of stating that a copy will be given to them as the model form states. The confidentiality section of the consent form will need to be appropriate for an online study. The participant should be aware that data sent over the Internet may not be secure. The participant should be told of any special procedures to protect the data such as encryption or not collecting IP addresses.