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>
Research Participant Information and Informed Consent From

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.

Contact Information: <Enter contact information for P.I. or other investigators>

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)

Brief Summary *required*

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation including why you might or might not want to participate, and to empower you to make an informed decision. You should feel free to discuss and ask the researchers any questions you may have.

You are being asked to participate in a research study of ... Your participation in this study will take about <included how much time will be required of participant and over what time> You will be asked to <brief summary of what is required in the study>

The most likely risks of participating in this study are <brief summary of potential risks>

The potential benefits to you for taking part in this study are < (*describe potential benefits*) **OR** You will not directly benefit from your participation in this study. However, your participation in this study may contribute to

understanding of your research question to the greater benefit>

General Guidelines for this section:

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. In general, the beginning of an informed consent would include a concise and brief explanation of the following:

- *(1) the fact that consent is being sought for research and that participation is voluntary;*
- *(2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;*
- *(3) any reasonably foreseeable risks or discomforts to the prospective subject;*
- *(4) any benefits to the prospective subject or to others that may reasonably be expected from the research; and*
- *(5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.*
- *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
- *This summary must be kept short.*

Purpose of this research: *required*

Any basic information included in the brief summary need not be repeated here.

- You are being asked to participate in a research study of… (include if there is additional information not included in the summary)
- You have been selected as a possible participant in this study because…
- From this study, the researchers hope to learn*…(brief summary of project)*
- Your participation in this study will take about _____. *(min., hours, wks, mos, or yrs.) (include if there is additional information not included in the summary)*
- *If appropriate:*
  - *Discuss how the researcher got the subject's name.*
  - If you are under 18, you cannot be in this study without parental permission.
  - In the entire study, ____ people are being asked to participate. *(provide number)*
  - *List any cooperating institutions (e.g.,*This study is being conducted collaboratively by Institution A and Institution B.*)*
  - *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.)*
  - *If your study involves incomplete disclosure or deception, the purpose section may be modified so as not to reveal the true purpose of the study. An alteration of consent must be approved by the IRB. Submit a debriefing form to be given to the subjects that explains the true purpose of the study. Often times during the debriefing process subjects are asked to re-consent to the research.*

What you will be asked to do: *required*

Any basic information included in the brief summary need not be repeated here.

If you decide to participate, you will <enter a detailed description of the participant's activities>.

General Guidelines for this Section:

- *Discuss what, if anything, the subjects have to do, not do in the study. Clearly delineate what is being done for research. For example, for education research, discuss what the subject has to do for the research and what is done for routine class work.*
- *Describe the procedures chronologically.*
- *If appropriate:*
  - *If your questions are going to be sensitive in nature, tell subjects about the types of questions they are going to encounter.*
  - *Tell subject if you are going to provide them with any or all findings.*

Potential Risks: *required*

Any basic information included in the brief summary need not be repeated here.

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

OR

General Guidelines for this Section:

- *Include risks in addition to physical risks, for example, legal, employment, psychological, social, economic, reputation, etc.*
- *Include risks associated with sensitive questions, for example, breach of confidentiality, or personal distress, or discomfort.*
- *Include risks of reporting illegal or compromising activities (e.g. sexual behavior).*
- *If appropriate:*
  - *If the risk is breach of confidentiality, address ways you are going to keep data confidential in the privacy and confidentiality section of the consent form.*
  - *Discuss the availability of referrals, counseling, or other services (e.g. suicide counseling).*

Potential Benefits: *required*

Any basic information included in the brief summary need not be repeated here.

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.

Your Right To Participate, Say No, Or Withdraw: *required*

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})

Privacy and Confidentiality: *required*

- *Discuss how you will maintain the subject's privacy throughout the project (e.g. private conversations).*
- The data for this project are being collected anonymously. Neither the researchers nor anyone else will be able to link data to you. **OR** The data for this project will be kept confidential.
  - *If the data are being coded and a key maintained separately, inform the subjects of the process.*
  - *If the data is identifiable (even if you are using a code), it is important to tell the subjects exactly who has access to the data and how you are going to protect their privacy and/or confidentiality)*
- Information about you will be kept confidential to the maximum extent allowable by law…***OR*** *something equivalent such as,* Although we will make every effort to keep your data confidential there are certain times, such as a court order, where we may have to disclose your data.
- *Discuss how you will keep the information about the subject confidential.*
  - *Where will the data be stored and how will it be protected?*
    - *If the data are being sent somewhere else (e.g. central data base, another institution), discuss.*
    - *If the data are being de-identified, discuss.*
    - *If you were to leave MGA, would you take a copy of the data with you? If yes, do not make the storage specific to MGA.*
  - *Who will have access to the data? The following entities must be listed:*
    - *Researchers and Research Staff.*
    - *Institutional Review Board (IRB).*
    - *Sponsors, agencies if applicable.- list names of organizations.*
- If appropriate:
  - *In some studies you should discuss required reporting (e.g. child abuse, elder abuse, MGA mandatory reporting protocols) or other circumstances under which their information will be released (e.g. suicide or homicide)…*unless there is a danger to yourself or others.
  - *For education projects, discuss how the instructors/teachers cannot access identifiable data.*
  - The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.
  - *If data are being collected via the internet, discuss if the data are being collected anonymously or with identifiers. Tell the subject if you are collecting IP addresses or not.*
  - *Certificates of Confidentiality are issued by the NIH to protect identifiable research information from forced disclosure. If a Certificate of Confidentiality is in effect, it should be reflected in the consent form. Participants should be given a fair and clear explanation of the protection that it affords, including limitations and exceptions [grants.nih.gov].*
  -

Costs And Compensation For Being In The Study: *required*

- *If appropriate:*
  - *Discuss any costs to the subject.*

    Procedures being performed for research purposes only will be provided free of charge by…
  - *Discuss any compensation (amount, timing) to the subject.*

- You will be compensated….
- You will receive…
- You will not receive money or any other form of compensation for participating in this study.

- *For research on students, tell the subject if they will receive credit or extra credit and include amount.*
- *Note for researchers: lotteries, drawings, or raffles may require a state gaming license by law.*

Alternative Options**:** *(If applicable, this is a required element of consent)*

- *The information included in the brief summary typically need not be repeated later in the body of the informed consent.*
- *If appropriate:*
  - *Discuss any alternatives to being in the research.*
  - *If students are required to obtain research credits, inform them of the equivalent, non-research assignment which may be done in place of research participation.*

How To Get Help If Injured: *(If applicable, this is a required element of consent)*
If you think you will need this section for your study, please contact the IRB

Research Results: *(Include only if applicable)*

- *If appropriate:*
  - *Tell subject if you are going to provide them with any or all findings (e.g. study findings, incidental findings for an individual subject).*

Future Research: *(This is a required element for any research that involves the collection of identifiable private information or identifiable biospecimens)*

- *Must include one of the two statements:*
  - Information that identifies you might be removed from the *<describe the identifiable private information or identifiable biospecimens>*. After such removal, the *<describe the information or biospecimens>* could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you *<or your legally authorized representative>*.
  - Your *<describe the information or biospecimens>* collected as part of the research, even if information that identifies you is removed, will not be used or distributed for future research studies.

Conflict of Interest: *(Include only if applicable)*
If appropriate (If there is a conflict of interest), the researcher should disclose this on the consent form (e.g. Significant financial interests, Affiliation with sponsor).

Contact Persons: *required*

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.

We will give you a copy of this consent form to keep. *(statement may be modified for an online setting)*

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.". Statement may be modified for an online setting)

_____ _____

Participant Date

ADDITIONAL SIGNUATRE ELEMENTS TO INCLUDE IF APPROPRIATE

- *If subjects will be identified, specific permission for identification must be obtained.*
  - I agree to allow my identity to be disclosed in reports and presentations.
    ☐ Yes ☐ No Initials_____
- *Inform subjects if they are being audiotaped or videotaped – indicate if this is required to be in the project, if not required, a separate check box with signature or initials is appropriate.*
  - I agree to allow audiotaping/videotaping of the interview.
    ☐ Yes ☐ No Initials_____
  - *Discuss how the tapes will be stored, protected, and when erased or destroyed.*

ADDITIONAL 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.]*~~

New OHRP guidelines prohibit exculpatory language in consent forms.

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.