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.
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<Enter department or school name>

earch ~~Participant Information and Informed Consent Form~~ ----------

<Enter title of study>

<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:

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

Purpose of this research: *required*

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

- x You are being asked to participate in a research study of… (include if there is additional information not included in the summary)
- x You have been selected as a possible participant in this study because…
- x From this study, the researchers hope to learn*…(brief summary of project)*
- x 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)*
- x *If appropriate:*
  - o *Discuss how the researcher got the subject's name.*
  - o If you are under 18, you cannot be in this study without parental permission.
  - o In the entire study, ____ people are being asked to participate. *(provide number)*
  - o *List any cooperating institutions (e.g.,*This study is being conducted collaboratively by Institution A and Institution B.*)*
  - o *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.)*
  - o *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:

- x *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.*
- x *Describe the procedures chronologically.*
- x *If appropriate:*
  - o *If your questions are going to be sensitive in nature, tell subjects about the types of questions they are going to encounter.*
  - o *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:

- o *Include risks in addition to physical risks, for example, legal, employment, psychological, social, economic, reputation, etc.*
- o *Include risks associated with sensitive questions, for example, breach of confidentiality, or personal distress, or discomfort.*
- o *Include risks of reporting illegal or compromising activities (e.g. sexual behavior).*
- x *If appropriate:*
  - o *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.*
  - o *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*

- x *Discuss how you will maintain the subject's privacy throughout the project (e.g. private conversations).*
- x 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.
  - o *If the data are being coded and a key maintained separately, inform the subjects of the process.*
  - o *If the data is identifiable (evr teiaMC /LBody /dy /MCID kparparpar y:D 10 > /LBody tcMC e (v)pD 1 ( )10 :-2 rflt*

- 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.*

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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

- 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:~~

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.

Last updated: May, 2020