Sample General Consent Form

Title of Study--required

Headings with (*) are required for all studies

IMPORTANT: BEFORE FINALIZING & PRINTING THIS DOCUMENT REMOVE THIS TEXT & ALL RED AND BLUE INSTRUCTIONAL TEXT

You are being asked to participate in a research study. Participation in this study is completely voluntary. Please read the information below and ask questions about anything you do not understand before deciding if you want to participate. A researcher listed below will be available to answer your questions.

RESEARCH TEAM*
Lead Researcher:
Name and Title
Department
Telephone Number

Faculty Sponsor:
Name and Title
Department

Other Researchers:
(List only those researchers qualified to be involved in the informed consent process)

Study Location(s):

PURPOSE OF STUDY*
The purpose of this research study is to… *(Complete this sentence) Examples include "to explore attitudes of first-generation Americans regarding education; to understand how social support influences mental health."*

SUBJECTS*
Inclusion Requirements
You are eligible to participate in this study if you… *(Complete this sentence or use a bulleted list of inclusion criteria) Examples include, "are at least 18 years of age or older," "are right-handed," "live in Claiborne County"*

Exclusion Requirements *(Optional)*
You are not eligible to participate in this study if you... *(Complete this sentence or use a bulleted list of exclusion criteria) Examples include, "do not have corrected 20/20 vision," " are taking high blood pressure medications," "are not enrolled in at least 9 hours at LMU".*

Number of Participants and Time Commitment*
This study will include approximately subjects and will involve approximately of your time.

PROCEDURES*
The following procedures will occur: *(Explain the research procedures in chronological order; include the expected duration of each procedure or each visit and the procedures to be completed at the visit.) Example:*
"You will complete a survey about your eating habits, then you will have your blood drawn (indicate amount) and your blood pressure taken".

RISKS AND DISCOMFORTS* *(Describe the risks and discomforts associated with the research study)*
[For minimal risk studies] This study involves no more than minimal risk. There are no known harms or discomforts associated with this study beyond those encountered in normal daily life.

OR

[For greater than minimal risk studies] The possible risks and/or discomforts associated with the procedures described in this study include: *(Complete this sentence. Categorize the risks by severity and include the likelihood of the risk/discomfort occurring. Make sure to consider all types of risks – psychological, social, economic, legal and physical.)*
Examples of risks/discomforts include: dizziness, nausea, embarrassment, social stigma (shame or disgrace), psychological distress, loss of employment, invasion of privacy and breach of confidentiality)

UNKNOWN RISKS *(Optional)*
There may be risks to being in this study that we don't know about now. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed. *[This section is required if the research involves clinical procedures or risk profile of research intervention is not well known.]*

BENEFITS*
Subject Benefits
As a participant, you may or may not benefit from participation in this study. The possible benefits you may experience from participation in this study may include . . . *(Complete this sentence – the description of subject benefits should be clear and not overstated) Examples: increase reading comprehension, improved writing skills, learning about ways to improve my memory.*

OR

[If no direct benefit to the subject is anticipated, delete the above statement and insert – You will not directly benefit from participation in this study.]

Benefits to Others or Society*
[*Insert a statement about possible benefits to science or society here. Example: a decrease in the number of children injured in car accidents, greater understanding of how stress influences memory.*]

ALTERNATIVES TO PARTICIPATION* *(Describe the alternatives)*
[If no alternatives] The only alternative to participation in this study is not to participate.

[If you intend to recruit students as subjects in this research project] Insert a statement such as "Participation in this research project is voluntary and will not positively or negatively affect your grade"

[If subjects will be compensated with extra course credit] The course instructor offering extra course credit for participation in research must provide alternatives to participation in this study. There will be no ill effects upon your standing in the class for non participation in the case that you choose not to participate, an alternative assignment will be provided that will allow you the opportunity to complete work requiring equal or less time and effort for the same amount of earned credit.

[Include if not a class assignment]
Your participation is voluntary. There is no penalty if you choose not to participate and you are free to withdraw at any time. [*Note that a subject cannot withdraw once an "anonymous" survey is submitted; however, a subject may choose not to complete the survey.]*

- *If applicable, add a statement such as* "There is no loss of benefits if you choose to withdraw" *or state how compensation will be prorated.*
- *If applicable, state that a subject may skip any questions they do not feel comfortable answering.*
- *If applicable, state that the subject may request the audio or video tape to be turned off at any time.*

COMPENSATION, COSTS AND REIMBURSEMENT*
Compensation for Participation*
[CHOOSE ONE OPTION]
You will be paid $ [*enter type of payment and amount of compensation*]

OR
You will be paid $ [*enter type of payment and amount of compensation*] after each study visit. There are [*enter # of study visits if applicable*] visits. Total payment for participation in this study is $[*enter total compensation for completion of the study*]. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed.

OR
[If subjects will not be compensated, please insert - You will not be paid for your participation in this research study.*]*

Costs *(Optional)*
There is no cost to you for participation in this study.

OR
You will be responsible for the following costs…*(Complete this sentence).*

Reimbursement *(Optional)*
You will be refunded for the following expenses that you incur…*(Complete this sentence)*
Examples: parking fees, transportation fees

If no reimbursement will be provided, delete the above statement and insert – You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

Compensation for Injury *– [Required if research involves greater than minimal risk]*
If you are injured as a direct result of your participation in this study, you will be provided reasonable and necessary medical care to treat the illness or injury at no cost to you or to your insurer/third party payer. Lincoln Memorial University does not routinely provide any other form of compensation for injury. It is important that you immediately report any suspected study-related illness or injury to the research team listed at the top of this form.

WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES *(Optional) [Required if subjects may be terminated by researcher and/or if there are adverse consequences (physical, social, psychological, economic, or legal) of the subject's withdrawal from the study]*

You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.

CONFIDENTIALITY*
Subject Identifiable Data* *(Explain whether subject identifiers will be linked to the research data.)* Examples include:

- All identifiable information that will be collected about you will be destroyed at the conclusion of the study.
- All identifiable information that will be collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.
- All identifiable information that will be collected about you will be kept with the research data.

Data Storage* *(Describe how the data will be maintained)*
Examples include:

- All research data will be maintained in a secure location at LMU. Only authorized individuals will have access to it.
- All research data will be stored on a laptop computer that [is password protected or has encryption software.]
- All research data will be stored electronically on a secure [computer or network] with [encryption or password] protection.
  Other privacy options:
- The [audio/video recordings] will also be stored in a secure location; then transcribed and erased as soon as possible.
- The [audio/video recordings] will also be stored in a secure location; then transcribed and erased at the end of the study.
- The [audio/video recordings] will also be stored in a secure location; then transcribed and erased at the end of the study.
- The [audio/video recordings] will also be stored in a secure location and transcribed. The recordings will be retained with the other research data.

Data Access* *(Explain who will have access to the research data)* **LMU Standard language**
The research team and authorized LMU personnel are guided by all HHS and FDA regulations concerning confidentiality and may have access to your study records to protect your safety and welfare. No information derived from this research project that personally identifies will be used

for any purposes and will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-LMU entities will not contain identifiable information about you. Publications and/or presentations that result from this study will not include identifiable information about you.

Data Retention* *(Explain how long the research data will be maintained)*

- The researchers intend to keep the research data until analysis of the information is completed.
- The researchers intend to keep the research data until the research is published and/or presented.
- The researchers intend to keep the research data for approximately __ years.
- The researchers intend to keep the research data indefinitely.
- The researchers intend to keep the research data in a repository indefinitely. Other researchers will have access to the data for future research.

OTHER CONSIDERATIONS *(Optional)*

Use of Specimens

[If the study involves collection of specimens, one of the following statements is required]

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of Lincoln Memorial University (LMU). Once you provide the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol.

OR

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of Lincoln Memorial University (LMU). Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

Investigator Financial Conflict of Interest

[If there could be the appearance of a conflict of interest, the following statement is required]

No one on the study team has a disclosable financial interest related to this research project.

NEW FINDINGS*

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the researcher team listed at the top of the form.

RETURN INSTRUCTIONS

- *Add any other instructions such as how to return the survey or consent forms (i.e. seal the consent form in the self-addressed envelope provided, return the survey to the instructor, etc.)*

IF YOU HAVE QUESTIONS*

If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.

If you are unable to reach a member of the research team listed at the top of this form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the Chair of the LMU IRB, Dr. Lori McGrew at (423) 869-6613, or by email irb@lmunet.edu.

VOLUNTARY PARTICIPATION STATEMENT*

You should not sign this form unless you have read it and have been given a copy of it to keep. Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with LMU or your quality of education provided to you by LMU. Your signature below indicates that you have read the information in this consent form and have had a chance to ask questions that you have about the study.

I agree to participate in the study.

Subject Signature Date

Printed Name of Subject

Legally Authorized Representative/Guardian Signature *Date*

Printed Name of Legally Authorized Representative/Guardian

Researcher Signature Date

Printed Name of Researcher