

APPENDIX A. STANDARD CONSENT FORM/INFORMATION SHEET TEMPLATE

TITLE OF STUDY

Investigators:	Full Name	Full Name	Full Name
Phone:	Phone #	Phone #	Phone #
E-mail:	e-mail	e-mail	e-mail

Purpose of the Study: *In this section please describe the specific purpose or aims of the study. Although you do not need to explicitly state your hypothesis, you should give a general sense of what you are investigating. It is in this section that you will indicate that the study involves research.*

See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).

Procedures: *In this section, you will inform participants about what they can expect to happen. Specifically, you should provide a step-by-step description of the specific study procedures including the method of recruitment, the informed consent process, as well as any study procedures they will be asked to complete. You should also give an overview of the types of questions that will be asked. Participants should also be informed about how long the procedures are expected to take.*

If the study involves more than one data collection period, this needs to be specified. You should discuss how many sessions they will be expected to attend, how long each session will last as well as when and how they will be scheduled.

See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).

Inclusion/Exclusion Criteria: *At minimum, this section should include the age range of participants. You may also include any procedures to which the subject must consent in order to participate in the study as well as any characteristics that must or must not be present for the participant to be eligible. To participate in this study, you must be <specify age range or minimum age>years. <Specify any other inclusion or exclusion criteria if applicable. Note also if there is any procedure that they must agree to do in order to participate; i.e., you must agree to ... in order to participate.>*

See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).

Risks/Discomfort: *In this section, you will inform participants about any risks (e.g., physical injury; loss of confidentiality) or discomforts (e.g., becoming upset) associated with their participation. Each potential risk or harm should be described in its own paragraph followed by an explanation for how that risk will be minimized. If there are no foreseeable risks, you may indicate this here.*

See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).

Benefits: *In this section, you should inform participants about the anticipated benefits of the research. Research benefits are the potential impact the study findings will have on understanding or treating a societal problem. Participants may benefit directly from their participation but this is not a requirement.*

See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).

Alternatives to Participation: *In this section, you inform participants that their participation is voluntary and that they have the right to withdraw or discontinue their involvement in the study at any time. If you are offering treatment, you must tell participants other ways they can get treatment without participating in the study. If students are being offered extra credit for their participation, then they must be offered other opportunities to earn extra credit without participating in the study.*

See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).

Cost Compensation: *In this section, you will inform participants either that they will not be compensated for their participation or how, when, and how much they will be compensated.*

See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).

Confidentiality: *Data collection can be considered anonymous when there is no reasonable way to link the person's identity to their responses either directly or through identifiers. If you are collecting identifying information and maintaining a list of names and unique identifiers so the person can be linked to their responses, then your study is confidential but NOT anonymous. In this section, you must describe the measures you are taking to ensure that the participants' data and identities are either anonymous or confidential. This includes methods of data collection, transmission (if data are being shared among 2 or more sites), entry, storage, and dissemination.*

For studies collecting sensitive information that, if released outside of the study, could place the person at risk for legal or civil liability or be damaging to their reputation or employability, PI's will be expected to obtain a certificate of confidentiality (COC) from the federal government. A COC protects the PI and his/her research team from being compelled by court order or subpoena to release any information about research participants. For information about COCs and how to apply for them, see XXX in the PI Instruction Manual. The federal government provides required language to include in consent forms that have COC's protecting the confidentiality of participant data.

If the study makes use of data panels, the PI should familiarize him/herself about the Data Privacy Policies and provide participants with a URL to those policies in case they want to become more informed about if/how the company managing the data panel makes use of any data collected.

See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).

Limits to Confidentiality (OPTIONAL): *If your study involves collection of reportable behavior or there is a risk of a medical injury, you will be required to include this section. See*

Contact Information: *Required language for this section is included below.*

If you have any questions regarding your rights as a research participant please contact the Institutional Review Board Chairperson, Dr. Elizabeth Katz, Office of University Research Services, 8000 York Road, Towson University, Towson, Maryland 21252; phone (410) 704-2236. If you have questions about the study or if you wish to withdraw your consent, please contact the Investigators, *<include PI and Co-PI's names and contact information or if the PI is a student, the name and contact information for the Faculty Advisor>*.

IF AN INFORMATION FORM IS BEING USED, INCLUDE THE FOLLOWING:

Thank you in advance for your participation!

Signed:

Signature

Faculty Advisor's Signature

IF A WRITTEN INFORMED CONSENT FORM IS BEING USED, INCLUDE THE FOLLOWING:

Disclosures:

By signing this consent form, I am indicating my understanding that (a) I am participating in a research study; (b) my participation is completely voluntary and that I can withdraw my consent at any time without penalty; and (c) I do not have to answer any questions I do not want to answer.

_____ I have read and understood the information on this form and have had any questions answered to my satisfaction

Subject's Signature Date

Witness to Consent Procedures Date

IF THE STUDY IS BEING CONDUCTED ONLINE, INCLUDE THE FOLLOWING:

By clicking YES below, I am indicating my understanding that (a) I am participating in a research study; (b) my participation is completely voluntary and that I can withdraw my consent at any time without penalty; and (c) I do not have to answer any questions I do not want to answer. If you do not wish to participate, please click NO.

APPENDIX B. CONSENT TEMPLATE RECOMMENDED/REQUIRED LANGUAGE

The recommended or required language for each section of the consent form is listed below. If specific language is not required, you are provided with some suggested stems to begin each sentence of the section. The standard consent form MUST INCLUDE all REQUIRED sections and may include OPTIONAL sections if appropriate.

Purpose of the Study (REQUIRED)

Suggested Stems

The purpose of this research study is to...

The current research study will investigate...

Examples

The purpose of this research study is to examine predictors and consequences of problematic substance use among college students.

The current research study is testing the effectiveness of two different approaches to enhancing the accuracy of eyewitness testimony

Procedures (REQUIRED)

Suggested Stems

If you decide to participate, you will be asked to... You will also be asked questions about... The entire study should take approximately...

Examples

If you decide to participate in this study, you will be asked to complete a number of paper and pencil, self-report measures. These questionnaires will ask about your personal characteristics, personality, drug and alcohol use, as well as sexual history. It should take you no more than 30 minutes from start to finish.

After providing informed consent, you will be assigned to either an experimental treatment group or a control group. You will not be told which group you have been assigned to.

If you agree to participate, you will be expected to come to the lab three times over a period of 6 weeks (i.e., once every two weeks). The first session (today) will take about 2 hours. The remaining two sessions will take no more than an hour each. A research assistant will contact you via text, e-mail and/or telephone to schedule each of your appointments. OR At the end of this session, the research assistant will schedule each of the follow up sessions.

Inclusion/Exclusion Criteria (REQUIRED)

Suggested Stems

In order to participate in this study, you must... You may not participate in this study if...

Examples

To participate in this study, you must be between the ages of 18 and 25 years. You must also agree to have your heart-rate recorded. You may not participate in the study if you are a current

smoker, have a history of cardiovascular or neurological disease, have known cardiac arrhythmias, or have a pacemaker.

Risks/Discomfort (REQUIRED)

Suggested Stems

To our knowledge, there is no risk (or possible harm) to you from your participation in this study.

There are some risks involved in this study that you should know about. One potential risk is...

RECOMMENDED/REQUIRED LANGUAGE

If the study may cause distress, use the following language (REQUIRED):

You may experience distress when answering certain questions or completing study procedures. If you become upset, you can discontinue the study at any time without penalty. You may also skip any questions you do not want to answer. If you are experiencing distress for any reason, whether related to the study or not,...

If participants are TU students on the Main Campus finish the stem as follows: ... you are encouraged to seek services through the Towson University Counseling Center. You may find information about the counseling center, as well as contact information, at the following website: <http://www.towson.edu/counseling/>. You will also be provided with a list of resources you can access if you are experiencing distress, whether or not it is related to your study participation. If you have a crisis at a time when TUCC is not available, please call the **National Suicide Prevention Lifeline 24/7 at 1 (800) 273-8255**.

If participants are TU students on the TUNE campus, finish the stem as follows: ... you may contact the Towson University Counseling Center (TUCC) on the main campus in Towson, MD for an evaluation. Following that meeting, staff at TUCC will refer you to a therapist in your local area. If you do not wish to travel to Towson, you may contact Margie Tversky (Phone: 410/704-3285; mtversky@towson.edu), Director of Student Services, who can help you with a referral to a community provider in your area. If you have a crisis at a time that it outside regular business hours, please call the **National Suicide Prevention Lifeline 24/7 at 1 (800) 273-8255**.

If participants are not TU students, finish the stem as follows: ...you are encouraged to see your own mental health provider (if you have one) or contact the **National Suicide Prevention Lifeline 24/7 at 1 (800) 273-8255**.

If the study involves the possibility of physical health consequences such as illness or injury, use the following language (RECOMMENDED):

There is a risk that you could <select one> get injured from completing the study procedure; experience a medical crisis. <list or describe all possible health risks involved> In the event this occurs, staff are trained to... <describe the credentials of the staff and their ability to handle a medical crisis; note any specialized medical devices, such as AEDs that are available> You must understand that neither the PI nor Towson University will pay for any medical care or hospitalization you may require from a research-related injury. You, and or your insurance, will have to pay for any medical costs incurred.

If there is a potential financial cost to participants (e.g., if the study involves sending text messages and participants are responsible for any costs incurred as a result, use the following language (RECOMMENDED):

The study involves sending text messages to you. You should understand that you will be responsible for covering the costs associated with sending or receiving text messages for the purposes of this research.

Benefits (REQUIRED)

Suggested Stems

You are not expected to benefit in any way from your participation in this research. However, the results of the study will help...

The current study will help us to... You may benefit from your participation by *<specify how>*

Examples

You are not expected to benefit in any from your participation in this study. However, results of this research will help us understand the factors that contribute to problematic substance use among college students.

The current study is intended to help use evaluate whether a new approach to treating social anxiety is effective. You may benefit from your participation in that you may experience an improvement in your symptoms of social anxiety.

Alternatives to Participation (REQUIRED)

Suggested Stems

If you do not want to participate in this study, ...

REQUIRED LANGUAGE ABOUT VOLUNTARY NATURE OF PARTICIPATION

Participation in this study is voluntary (that is, it is up to you whether or not to participate). You are free to withdraw or discontinue participation in this study at any time without...

<choose one of the following to end the second sentence> affecting any compensation to which you are already entitled; affecting your standing with the university or your grade in your class; penalty.

You may also choose not to answer any questions that you do not want to answer.

REQUIRED LANGUAGE ABOUT ALTERNATIVE TO PARTICIPATION

If you do not want to participate in this study...

<choose one of the following to end this sentence if treatment is provided or extra credit in a course is awarded> you may seek services through; you will be given other opportunities to earn extra credit in this course;

<if there is no treatment provided and no extra credit awarded, use the following>, then do not sign this consent form; click NO at the bottom of this page.

Cost Compensation (REQUIRED)

Suggested Stems

You will receive no compensation for your participation in this study.

To compensate you for your time, you will receive

Examples

You will receive no compensation for your participation in this study.

In order to compensate you for your time, you will...

...receive X point(s) of extra credit on your final exam.

...receive \$10 in cash once you have completed all study procedures

...\$10 gift cards for each study session you complete for up to a total of XX\$ if you complete all study sessions.

Confidentiality (REQUIRED)

REQUIRED LANGUAGE

<For confidential studies> To ensure the confidentiality of the data you provide, your responses will be coded using a unique identification number. A master list that links your name and unique identification number will be maintained in a locked file cabinet in the PI's office and will be accessible only to study staff. *<also include anyone else who may have access to the data; e.g., for federally funded studies, the funding agency may request to see deidentified data>* This list will be destroyed *<specify either>* after data collection has been completed *<or>* after a period not to exceed XX years after the study has been completed.

<For anonymous studies> To ensure your anonymity, we are not collecting any identifying information that could be used to identify you. *<If you are using an online data collection platform>* The program used to house the questionnaire will be set to remove all identifying information from the dataset including IP addresses. *<In addition, include the following>* The consent form, which has your name on it, will be stored separately from the rest of your data. We ask that you NOT place your name or other information that could identify you on your questionnaires. Any publications or reports that result from this research will not include identifying information on any participant.

<Language required for online studies> The data are being collected via the online platform *<specify>*. To address any concerns you may have about the confidentiality of data collected in this manner, please see *<specify the company's>* Data Privacy Policy at *<include the URL here>*. You should specifically look at the section entitled, *<direct participants to the relevant section of the data privacy policy.>*

<Language required for studies involving data panels> If you are a member of a data panel, the extent to which your confidentiality is guaranteed depends upon the Data Privacy Policy that you agreed to when signing up as a panel member. You should be certain to revisit the privacy policy to familiarize yourself about how/if the company managing the data makes use of any data collected by its customers.

Limits to Confidentiality (OPTIONAL)

REQUIRED LANGUAGE

<Include some or all of the following, as relevant> Although we will do everything we can to assure your confidentiality, the researchers are bound by Maryland law to report to Maryland Child Protective Services as well as the University President or her designee, any instances of child or elder abuse (including sexual, physical, or emotional abuse as well incest) and neglect,

regardless of when they occurred and regardless of whether you, or someone else, are/were the victim or perpetrator. The researchers are also required to intervene on your, or an intended victim's, behalf should you indicate an intention to harm or kill yourself or someone else. University System of Maryland policy also requires that the researchers inform University Officials about any instances of sexual contact between students and either faculty or staff members. Finally, in the event of a medical emergency, the research team is permitted to release any information about you that is necessary to ensure that you receive adequate medical care.