This template has been developed to help researchers write a complete informed consent document that will include required information, utilize an accepted format, and use suggested language approved by the Truman State University Institutional Review Board (IRB).

INSTRUCTIONS FOR DEVELOPING AN INFORMED CONSENT DOCUMENT

**TEXT FOUND THROUGHOUT THIS DOCUMENT IN BOLDFACE AND BRACKETS OFFERS GUIDANCE AND SUGGESTIONS. DELETE THIS TEXT AND REPLACE IT WITH THE APPROPRIATE WORDING FOR YOUR PROJECT.**

The informed consent document template that follows is for use with research participants. This template contains all of the elements of informed consent required by the federal guidelines and additional language required by the Truman State University IRB.

Language of the Informed Consent Document

Many informed consent documents contain language that is too technical or scientific to be understood by research participants. Please write the consent document in language that can be understood by a middle school student; *always* include easily understood definitions, examples, and/or equivalents when technical terms are used. Please keep sentences short and concise.

This template is written in the second person (e.g., “You are being invited to take part in…”). **If your research project involves more than one population of study** (parents and children, ill participants and healthy controls), please consider writing the informed consent document in the third person to eliminate the need for a different version for each population (e.g., “We are inviting people to participate…” rather than “You are invited…” and “Your child is invited…”). However, in studies where procedures are markedly different for each population, a separate consent document for each population may be preferable. Please contact the IRB Administrator with any questions at (660) 785-7245 or irb@truman.edu

Additional Information in the Appendix

Following the basic informed consent document template is anAppendix entitled **“Suggested Wording for Specific Issues**,” which contains accepted language for specific issues not addressed in the basic template (like audio or videotaping participants). Please use the suggested wording in these sections as appropriate to your project.

Informed Consent Document

Project Title: **[Title]**

Principal Investigator: **[Name and department] If you are a student, identify yourself as such.**

Co-Investigator(s): **[Name and department of other individuals responsible for the conduct of this project] If co-investigators are students, identify them as such.**

# WHAT IS THE PURPOSE OF THIS STUDY?

You are being invited to take part in a research study designed to **[include up to four sentences providing a general description of the project, addressing these four points 1) what is being investigated; 2) what knowledge or information is being sought; and 3) how the results/outcomes are intended to be used (e.g., student thesis, publication, presentation)]**.We are studying this because **[include the significance of this project using terminology that is easily understood]**.

This consent form gives you the information you will need to help you decide whether to be in the study or not. You may ask any questions about the research, the possible risks and benefits, your rights as a volunteer, and anything else that is not clear. When all of your questions have been answered, you can decide if you want to participate in this study or not.

You are being invited to take part in this study because **[complete this statement by describing (in one or two sentences why the person reading this informed consent document is a possible participant for your project; be sure to include any specific inclusion and/or exclusion criteria.) For example: …are taking an introductory psychology class, …are a teacher in the Kirksville school district, …are a jogger, …are a healthy adult, etc.]**

You must be 18 years or older to participate in this study. **[add this statement if your participants are adults.]**

### WHAT WILL HAPPEN DURING THIS STUDY AND HOW LONG WILL IT TAKE?

**[Describe briefly what is going to happen to the participant and what you are going to ask the participant to do if he/she participates. Describe where the procedures will take place (e.g., participant’s home, classroom building on campus, your office, etc.) *Use subheadings as appropriate.* For complex projects, consider including a chart or table showing which procedures/tests are performed at each visit.]**

If you agree to take part in this study, your involvement will last for **[approximate length of time for one subject’s participation (in minutes or hours). If more than one visit or contact is involved in the study, give the total number of visits, the approximate length of time for each contact, and length of time between each visit.]**

### WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY?

The possible risks and/or discomforts associated with the procedures described in this study include: **[describe any potential risks – which include the potential for psychological, emotional, physical, pain, legal, privacy issues, etc. Depending on the type of study, some risks may be better described as things that could make the participant “uncomfortable” – such as fatigue or embarrassment. Be sure to include procedures that will be followed to minimize identified risks. If there are no known risks, state that there are no foreseeable risks to participating.]**

**[We do not know if you will benefit from being in this study.] ---OR--- [You will not individually benefit from being in this study.]** However, we hope that, in the future, other people might benefit from this study because **[describe in one sentence why others might benefit in the future from the knowledge that will be gained. Note that compensation is not a benefit and should be described in the following section.]**

You **[will / will not]** be paid for being in this research study. **[Clearly describe the monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.). If compensation is pro-rated when a participant withdraws prior to completing the study, explain how it is pro-rated. Describe any non-monetary compensation (e.g., extra credit, gift certificate), separately from monetary compensation and include the approximate value.]**

### CONFIDENTIALITY/ANONYMITY

The information you provide during this research study will be kept confidential to the extent permitted by law. To help protect your confidentiality, we will **[describe the methods you will use to help ensure confidentiality, e.g., using participant initials or identification code numbers only on data forms, having locked filing cabinets and storage areas, using password-protected computer files].**

If the results of this project are published your identity will not be made public **[if they could be identified in any way, specifically note that here].**

### DO I HAVE A CHOICE TO BE IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. **[Add the following, if applicable: If you decide not to take part in this study, your decision will have no effect on the quality of care, services, etc., you receive.]**

You will not be treated differently if you decide to stop taking part in the study. **[If the study involves interviews, surveys, or questionnaires, include a statement that the participant is free to skip any questions that he/she would prefer not to answer.]**

If you have any questions about this research project, please contact: **[name, phone number and email address of primary investigator (and co-investigators/faculty sponsor, if applicable) You must list your faculty sponsor’s name and contact information if you are a student]**.

If you have questions about your rights as a participant, please contact the Truman State University Institutional Review Board Administrator, at (660) 785-7245 or by email at irb@truman.edu

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You may receive a copy of this form upon request.

**[If your study does not require a signed consent document, then remove the name/signature lines below and change the above language to: “Proceeding to the survey indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in the study.”]**

Participant's Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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(Signature of Participant) (Date)

**[Note to Researchers: Please check the Appendix below for any additional information that may be pertinent to your project.]**

**APPENDIX**

**SUGGESTED WORDING FOR SPECIFIC ISSUES**

The appropriate text should be used in the appropriate area of the informed consent document. The suggested wording below should be modified appropriately for the specifics of your study.

**Alphabetical list of appendix sections by topic:**

**Confidentiality: WHO WILL SEE THE INFORMATION I GIVE?**

 *Audio/Video Recording/Photographs*

 *Confidentiality: coding or using numbers*

 *Future Use of Personal Information*

 *Reporting Violence, Abuse, or Self-Inflicted Injury*

**Procedures: WHAT WILL HAPPEN IN THIS STUDY?**

 *Blood Collection*

 *Placebo*

**Risks: WHAT ARE THE RISKS OF THIS STUDY?**

 *Email*

 *Injury*

 *Internet*

 *Unforeseeable Risks*

**POTENTIAL FOR FOLLOW-UP STUDIES**

 *Follow-Up Studies*

**Voluntary Participation: DO I HAVE A CHOICE TO BE IN THIS STUDY?**

 *New Information*

 *Termination of Study by Investigator*

**Vulnerable Population: Prisoners: WHAT IF I HAVE QUESTIONS?**

**CONFIDENTIALITY: WHO WILL SEE THE INFORMATION I GIVE? section:**

**Audio/Video Recording/Photographs**

One aspect of this study involves making **[audio recordings / video recordings / photographs]** of you. **[Then describe why the recordings/photos are being made, who has access to them, and if or when they will be destroyed.]**

### Confidentiality: coding or using numbers

To help protect your confidentiality, we will **[describe the methods you will use to help ensure confidentiality, e.g., using subject initials or identification code numbers only on data forms, having locked filing cabinets and storage areas, using password-protected computer files.]**

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

**Future Use of Personal Information**

**[Sample language – modify as appropriate to your study:]**

It is possible that we may want to include personal information obtained from you during your participation in this study in future studies. This information may be in the form of statistical information, which does not identify you or your personal information may be included in a database, with your identity included. We are requesting your permission to use your personal information in the future. Because it is not possible for us to know what studies may be a part of our future work, we ask that you give permission now for us to use your personal information without being contacted about each future study. If you agree now to future use of your personal information, but decide in the future that you would like to have your personal information removed from research database, you should contact **[name and phone number of PI]**.

**[If subjects can participate in the main study without giving permission for future use of personal information, add a “yes/no” check box for the participant to indicate whether permission is being given. If other investigators/groups may have future access to the individual’s personal information, this possibility should be described.]**

**Studies Focusing on Violence, Abuse, or Self-Inflicted Injury**

**[Add this sentence to the text of the standard Confidentiality section – does not need heading:]** Missouri law requires that certain trained individuals (mandated reporters) disclose to the proper authorities any information shared with them concerning elder abuse, abuse of mentally ill or developmentally disabled persons, child abuse, or child sexual abuse. **[Indicate if one or more of the researchers conducting this project is a mandated reporter.]** The researcher may also report threats of harm to self or to others. Except as explained above, all information gathered during this research project is confidential to the extent permitted by law.

**PROCEDURES: WHAT WILL HAPPEN IN THIS STUDY? section**

### Studies Involving Blood Collection

**[Sample language – modify as appropriate to your study:]**

During the course of this study a total of **[indicate cumulative amount in lay terms, (e.g., 80 ml which is just over 1/3 of a cup of your blood)]** will be taken from you. At each session only **[indicate amount in lay terms (e.g., 15 ml which is just over 1 tablespoon)]** will be taken. The blood will be drawn by **[include the qualifications for the individual who will be drawing the blood].** Your blood **[will be used / analyzed – select the appropriate phrase]** for **[include all uses for the blood or analyses to be conducted]** by **[indicate who will be using or analyzing the samples and how the samples will be coded.**

Potential risks associated with blood draws include temporary discomfort from where the needle is inserted into your arm, bruising around the site where the blood was taken from, and rarely infection. To minimize these risks you will be instructed to **[include appropriate procedures]**.

#### Use of Placebo

You may receive a placebo (an inactive substance) if you participate in this study. This means that it is possible that no medication will be received while participating.

 **RISKS: WHAT ARE THE RISKS OF THIS STUDY? section**

#### Studies Involving Email

Email transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses.

##### Studies Involving Potential for Physical Injury

In the event of research related injury, compensation for medical treatment is not provided by Truman State University or the researchers.

#### Studies Involving Use of the Internet

Secure transmission of information via the Internet cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, or destroyed.

**Unforeseeable Risks**

In addition to the side effects specifically described in the “What are the Risks of this Study?” section of this document, you might experience currently unknown side effects from the procedures used in this research.

**Potential for Follow-Up Studies section**

**[If applicable, this section should be placed above the participant’s signature line.]**

There is a chance you may be contacted in the future to participate in an additional study related to this project, which will require the researchers to retain your contact information after this study has been completed. If you would prefer not to be contacted, please let the researchers know, at any time. **If you are contacted, you can choose whether or not to participate.**

 **DO I HAVE A CHOICE TO BE IN THIS STUDY? section:**

## New Information

[Include this section if there is a potential for new information to become available during the course of this study that may affect a participant’s willingness to be a part of the study. For example, if the project involves the use of caffeine supplements and during the course of the study the same level of caffeine supplementation is determined by other studies to be harmful to certain populations, a participant may choose to withdraw.]

If we obtain new information during the course of this study that might affect willingness to participate, you will be promptly informed.

**Termination of Study by Investigator/Sponsor**

Under certain circumstances, your participation in this research study may be ended without your consent. This might happen because **[describe why the study might be ended without the participant’s consent]**.

### SPECIAL INFORMATION FOR PRISONERS WHO PARTICIPATE IN THIS STUDY

### [Make this a separate section before WHAT IF I HAVE QUESTIONS?]

If you take part in this research study, your participation will not affect or influence the length of your sentence, your parole, or any other aspect of your incarceration. Likewise, if you decide not to participate, or if you leave the study before it is over, **your participation will have no influence on your incarceration.** **[If applicable, add: If you complete your sentence while participating in this study, you may continue to participate afterwards. (Then describe how participation would continue if the prisoner is released during the study. Also describe any changes in Costs and Compensation that may occur should the subject be released from prison during the course of the study.)]**