Instructions for consent form:

1) The purpose of this template is to assist investigators and other research personnel in creating informed consent documents and to facilitate consistency and accuracy of informed consent language between human subject research protocols.

2) This template is intended to be a guide. **However, all investigators must follow this format, order, and language where provided in each consent document.** All of the elements required by Federal and Institutional statute are included.

3) *Required fill-ins and instructions are italicized*; **bold headings** and plain text indicate required language. Please delete all italicized or non-relevant text prior to submission.

4) What is included here is a **consent** document, designed for adults.

5) For children (under 18), **assent** needs to be obtained as well as **consent** from parent or guardian. **Assent** should be a few simple paragraphs that you include as a separate document in your submission (clearly labeled: ASSENT DOCUMENT outlining what you will tell each child before they take part in your study. It should explain everything you will be asking them to do and that they can stop at any time. You are expected to get their personal permission to participate (assent) before you use them as subjects. Also, please include specific information regarding referral(s) to professional consultation if your project has potential for causing strong feelings in participants (i.e.: questions regarding sexual activity, sexual orientation, physical abuse, drug and alcohol use, suicidal thoughts, etc.).

6) Please note:
If you are using Video or Audio Recordings of subjects in your research, you must clearly state each of the following in your Informed Consent Document:

1. Who will have access to the recordings?
2. Where the recordings will be stored?
3. What will happen to the recordings after the project has terminated?
4. How will the recordings be used in data analysis?

If your document does not address all these items, the IRB will not approve it.

7) Please refer to the **Guidelines for Informed Consent Forms** for additional guidance. **Standard Statements** related to procedures, minors, genetics, and other issues that may need to be addressed on a study specific basis are also available. Standard statements must be used for “Procedures” and “Discomforts and Risks” unless supplied by the proposed grant agency. You may use additional wording as needed.

University of Pikeville Institutional Review Board (UPIKE IRB)
Informed Consent Form for Research Involving Human Subjects

Protocol Title:

Principal Investigator:

UPIKE *[enter college and department]*:

Please add the following information to the introduction of all informed consents that involve children and adults.

In this consent form, "you" always means the study subject. If you are a legally authorized representative (such as a parent or guardian), please remember that "you" refers to the study subject.

Ensure that the pronoun "you" is used throughout the informed consent. Avoid the use of the phrase "you/your child."

1. Introduction

You are being asked to take part voluntarily in the research project described below. Please take your time making a decision and feel free to discuss it with your friends and family. Before agreeing to take part in this research study, it is important that you read the consent form that describes the study. Please ask the study researcher or the study staff to explain any words or information that you do not clearly understand.

2. Why is this study being done?

You have been asked to take part in a research study of *insert simple explanation or purpose of study.*

Approximately, *enter number of study subjects,* will be enrolling in this study at UPIKE *(or other if not on campus)*. *If this is a multicenter trial, enter the total number of people enrolled at the total number of sites.*

You are being asked to be in the study because *enter the reason a subject qualifies for the study. [Example: you are a male over the age of 18 in the Psychology program]*

If you decide to enroll in this study, your involvement will last about *enter the length of the study (in days or weeks) for a single subject.*

3. What is involved in the study?

If you agree to take part in this study, the research team will: *Describe all procedures, and any review of records, interviews, questionnaires, etc. that will take place.*

4. What are the risks and discomforts of the study?

There are no known risks associated with this research

(Alternatively, describe any known physical and nonphysical risks and/or discomforts. Use IRB Standard Statements if available.)

If applicable, state: The study may include risks that are unknown at this time.

5. What will happen if I am injured in this study?

The University of Pikeville and its affiliates do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness. You will not give up any of your legal rights by signing this consent form. You should report any such injury to *(put the principal investigator's name and phone number here)* and to the UPIKE IRB at (606-218-5527) or ritathacker@upike.edu.

6. Are there benefits to taking part in this study?

There will be no direct benefits to you for taking part in this study. *(Add any educational or informational benefits as desired, such as:* This research may help us to understand *and enter a very brief description)*

7. What other options are there?

You have the option not to take part in this study. There will be no penalties involved if you choose not to take part in this study.

8. Who is paying for this study?

Internal Funding:

Funding for this study is provided by *state the name of the college, department or grant.*

External funding:

UTEP and *list the names of the investigators* are receiving funding from *list the name of the sponsor or organization* to conduct this study.

9. What are my costs?

There are no direct costs. You will be responsible for travel to and from the research site and any other incidental expenses.

10. Will I be paid to participate in this study?

If payment:

You will be paid *insert dollar amount* for participation in this study.
Describe payment schedule – consider using a table or graph format.

If payment with minor involved:

You will be paid *insert dollar amount*, for participation in this study.

Your child will also be paid for their participation in the form of *insert dollar amount, gift certificate, savings bond, etc*

If no payment:

You will not be paid for taking part in this research study.

11. What if I want to withdraw, or am asked to withdraw from this study?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, there will be no penalty.

If you choose to take part, you have the right to stop at any time. However, we encourage you to talk to a member of the research group so that they know why you are leaving the study. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

The researcher may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, AND *list other reasons that the study may be stopped*.

12. Who do I call if I have questions or problems?

You may ask any questions you have now. If you have questions later, you may call insert *study contact(s)* at *insert phone number, cell phone number, email address, and/or pager*.

If you have questions or concerns about your participation as a research subject, please contact the UPIKE IRB at (606-218-5219) or cathythornsbury@upike.edu.

13. What about confidentiality?

1. [*Describe the way confidentiality of records identifying the subject will be maintained. Use words to the following effect, if appropriate*:] Your part in this study is confidential. None of the information will identify you by name. All records will [*describe how records are to be maintained*].

2. [*Or, if the study involves information that legally must be reported to government agencies, then include the following*:] Every effort will be made to keep your information confidential. Your personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include, but are not necessarily limited to:

- The sponsor or an agent for the sponsor
- Department of Health and Human Services
- UPIKE IRB

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

All records will be [*describe how they are to be maintained*].

3. [*Alternatively, if the study is anonymous, then this should be stated here. Indicate to the subject how anonymity will be preserved.*]

14. Mandatory reporting

If there is a reasonable chance that information may be elicited concerning child abuse or neglect, or potentially dangerous future behavior to others as part of the research protocol, the following disclosure must be made:

If information is revealed about child abuse or neglect, or potentially dangerous future behavior to others, the law requires that this information be reported to the proper authorities.

15. Authorization Statement

I have read each page of this paper about the study (or it was read to me). I know that being in this study is voluntary and I choose to be in this study. I know I can stop being in this study without penalty. I will get a copy of this consent form now and can get information on results of the study later if I wish.

Participant Name: _____ Date:

Participant Signature: _____ Time: _____

Participant or Parent/Guardian Signature: _____

Consent form explained/witnessed by: _____

Signature

Printed name: _____

Date: _____ Time: _____