**Example of Parent-Guardian Informed Consent Statement**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Name of the Study)

**KEY INFORMATION**

* This project is studying\_\_\_\_\_\_\_\_\_.
* Your child’s participation in this research project is completely voluntary.
* Your child’s participation will take \_\_\_\_\_\_\_\_ minutes/hours/days.
* Your child will be asked to do the following procedures: *[List procedures here].* More detailed information on the procedures can be found below.
* *[List possible risks or discomforts related to the study. If none, add statement explaining no risks or discomforts.]*
* *[List possible benefits to subjects or others. If none, add statement explaining no benefits.]*
* *[List alternatives to participating. If no alternative, state “Your child’s alternative to participating in this research study is not to participate.”]*

INTRODUCTION

The Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at the University of Kansas supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish your child to participate in the present study. You may refuse to sign this form and not allow your child to participate in this study. You should be aware that even if you agree to allow your child to participate, you are free to withdraw at any time. If you do withdraw your child from this study, it will not affect your relationship with this unit, the services it may provide to you, or the University of Kansas.

PURPOSE OF THE STUDY

*Insert description of the purpose of the study.*

PROCEDURES

*Insert description of the procedures that will be followed in the study. Address the participants, i.e. “you (your child) will be asked to…” Include the time commitment involved.*

*If you plan to use video or audiotapes, please state so here. Participants must be given the option of having taping stopped at any time. Inform the parent whether or not these recordings are required for his/her child’s participation in the study procedures. (If recording is optional, provide a space at the end of the consent document where the parent initials to consent specifically for the audio and/or video recording.) Explain who will be transcribing the recordings, who will have access to the recordings, where the recordings will be stored (security), and if and when the recordings will be erased/destroyed.*

RISKS

*Insert a description of all burdens, inconveniences, pain, discomforts and risks associated with participation in the study. If no risks are anticipated, this should be stated explicitly.*

BENEFITS

*Insert a description of the potential benefits, if any, to the research subject. Clarify if these are direct benefits (e.g., to the subject), or indirect benefits, (e.g., to society). If there are no anticipated benefits, this should be stated explicitly.*

PAYMENT TO PARTICIPANTS

*Insert a statement regarding whether or not participants will be paid and if so, how much and on what schedule. Insert the following statement if participants are being paid:*

*Investigators may ask for your social security number in order to comply with federal and state tax and accounting regulations.*

PARTICIPANT CONFIDENTIALITY

*Include a general statement about confidentiality, such as:*

Your child's name will not be associated in any publication or presentation with the information collected about your child or with the research findings from this study. Instead, the researcher(s) will use a study number or a pseudonym rather than your child's name. Your child’s identifiable information will not be shared unless (a) it is required by law or university policy, or (b) you give written permission.

*Indicate how long the researcher plans to use or disclose the information and include an expiration date. If there is no expiration date, state that there is no expiration date.* For example, "Permission granted on this date to use and disclose your information remains in effect indefinitely. By signing this form you give permission for the use and disclosure of your child's information, excluding your child's name, for purposes of this study at any time in the future."

PRIVATE INFORMATION (DATA) AND/OR BIOSPECIMENS – FUTURE RESEARCH USE

*Include this section if you are collecting private information and/or biospecimens from participants.*

*Explain if identifiers might be removed and used for future research use. Use one of the following examples:*

*Example 1:* Your child’s identifiable information may be removed from the data and/or biospecimens collected during this project, and the de-identified data and/or biospecimens will be used for future research without additional consent from you.

*Example 2:* Your child’s identifiable information and/or biospecimens will not be used or distributed for future research studies even if your identifiable information is removed.

*For research involving biospecimens, explain if the participant’s biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

*For research involving biospecimens, explain whether the research might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*

INSTITUTIONAL DISCLAIMER STATEMENT

*Required only if the study involves discernible risks to subjects –* "In the event of injury, the Kansas Tort Claims Act provides for compensation if it can be demonstrated that the injury was caused by the negligent or wrongful act or omission of a state employee acting within the scope of his/her employment."

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you are receiving or may receive from the University of Kansas or to participate in any programs or events of the University of Kansas. However, if you refuse to sign, your child cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

*Be sure to consider the length of time the data will be collected and include whether you will use information that was collected prior to the parent’s cancellation of permission. For example:* You may withdraw your consent to allow participation of your child in this study at any time. You also have the right to cancel your permission to use and disclose further information collected about your child, in writing, at any time, by sending your written request to: *Fill in name and campus address of Researcher here.*

If you cancel permission to use your child's information, the researchers will stop collecting additional information about your child. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above.

QUESTIONS ABOUT PARTICIPATION

Questions about procedures should be directed to the researcher(s) listed at the end of this consent form.

PARTICIPANT CERTIFICATION:

I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study. I understand that if I have any additional questions about my child's rights as a research participant, I may call (785) 864-7429, write to the Human Research Protection Program (HRPP), University of Kansas, 2385 Irving Hill Road, Lawrence, Kansas 66045-7568, or email irb@ku.edu.

I agree to allow my child to take part in this study as a research participant. By my signature I affirm that I am at least 18 years old and that I have received a copy of this Consent and Authorization form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type/Print Participant's Name Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian Signature

[If signed by a personal representative, a description of such representative’s authority to act for the individual must also be provided, e.g. parent/guardian.]

Researcher Contact Information

John Doe J.D. Smythe Ph.D.18

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Human Studies Dept. Human Studies Dept.

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Lawrence, KS 66045 Lawrence, KS 66045

785 864 \_\_\_\_\_\_\_\_ 785 864 \_\_\_\_\_\_\_\_\_\_