**Example of Informed Consent Statement/HIPAA Authorization**

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(Name of the Study)

* This project is studying \_\_\_\_\_\_\_\_\_.
* Your participation in this research project is completely voluntary.
* Your participation will take \_\_\_\_\_\_\_\_ minutes/hours/days.
* You 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. For SONA, this may be an alternative assignment or alternative research study. If no alternative, state “Your 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 to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree to participate, you are free to withdraw at any time. If you do withdraw 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 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 subjects whether or not these recordings are required to participate in the study procedures. (If recording is optional, provide a space at the end of the consent document where subjects initial 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.*

**INFORMATION TO BE COLLECTED** *(This section must include a description of the information to be used and disclosed, which identifies the information in a specific and meaningful fashion).*

To perform this study, researchers will collect information about you. This information will be obtained from: [insert description, e.g., your medical record at Clinic X, a health history taken by the researcher, a physical exam conducted by the researcher, a health questionnaire]. Also, information will be collected from the study activities that are listed in the Procedures section of this consent form.

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

Your name will not be associated in any way with the information collected about you or with the research findings from this study. The researcher(s) will use a study number or a pseudonym instead of your name.

The information collected about you will be used by: [list the PI and the class of other persons or groups authorized to use and/or disclose the information internal to the University, Lawrence Campus, e.g., Dr. X, members of the research team, the KU healthcare facility collaborating in the study, KU’s Center for Research and officials at KU that oversee research, including committees and offices that review and monitor research studies.]

In addition, Dr. X and [his/her/their] team may share the information gathered in this study, including your information, with: [list the persons or groups external to the University, Lawrence Campus, with whom the researchers may share or disclose the information, e.g. collaborating researchers, colleagues, representatives of Sponsor Name (the sponsor of the study). Include a statement about the purpose of these disclosures). Again, your name would not be associated with the information disclosed to these individuals. [The following sentence is required only if protected health information subject to HIPAA’s Privacy Rule will be disclosed: Some persons or groups that receive your health information as described above may not be required to comply with the Health Insurance Portability and Accountability Act’s privacy regulations, and your health information may lose this federal protection if those persons or groups disclose it. See Instructions for Submitting Applications to the Human Subjects Committee for more information on use and disclosure of protected health information.]

The researchers will not share information about you with anyone not specified above 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 information for purposes of this study at any time in the future."

**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/their 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, you cannot participate in this study.

**CANCELING THIS CONSENT AND AUTHORIZATION**

You may withdraw your consent to participate in this study at any time. You also have the right to cancel your permission to use and disclose information collected about you, in writing, at any time, by sending your written request to: [Name and address of Researcher]. If you cancel permission to use your information, the researchers will stop collecting additional information about you. 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 and the use and disclosure of information about me for the study. I understand that if I have any additional questions about my rights as a research participant, I may call (785) 864-7429 or write the Human Research Protection Program (HRPP), University of Kansas, 2385 Irving Hill Road, Lawrence, KS 66045-7563, email irb@ku.edu.

I agree to take part in this study as a research participant. I further agree to the uses and disclosures of my information as described above. 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.

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Type/Print Participant's Name Date

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

Participant's 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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University of Kansas University of Kansas

Lawrence, KS 66045 Lawrence, KS 66045

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