# Oral Consent Procedures

*Appropriate in situations where cultural issues may necessitate a more informal process*

Oral consent is a waiver of the documentation of consent; however, it is not a waiver of consent. HRPP may waive the requirement of a signed consent form when:

1. The research presents no more than minimal risk and is conducted under circumstances where a written consent procedure is not normally required, OR
2. The only risk to the participants is a breach of confidentiality resulting from the documentation of identity on the consent document.

Although a participant may not sign a form, federal regulations still require that he/she is informed of the study and provides consent to participate. Your oral consent procedure **must** include the following:

* A concise and focused presentation of the **key information** that is most likely to assist a prospective subject in understanding the reasons why one might/might not want to participate in research
* A statement that the study involves ***research***
* An explanation of the ***purposes*** of the research
* The expected ***duration*** of the subject’s participation
* A description of the ***procedures*** to be followed
* A description of reasonably foreseeable ***risks***
* A description of any ***benefits***
* A statement describing how the participant’s identity will be protected
* A statement describing if data/specimens will be deidentified and distributed for future research use
* Your name and contact information (students should include faculty supervisor contact information)
* HRPP contact information where subjects can direct questions regarding their rights
* A statement that participation is ***voluntary*** and involvement may be discontinued at any time without penalty
* *A statement regarding internet security (applicable for interviews conducted via Voice over Internet Protocol (VoIP) such as Skype)\**
* *Information regarding audio/visual recording (when applicable)\*\**

Please note that the above elements do not constitute an exclusive list. When appropriate, HRPP may request that additional elements of information be provided to each subject.

*There is no requirement that the consent designee or a witness sign the oral consent script itself as evidence that the consent discussion took place. However, the PI must keep a record that consent was obtained, when it was obtained, where, and by whom. This record may or may not include the identification of the study subject, depending upon IRB requirements.*

**Please use the template on the following page.**

# Sample Oral Consent

* 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.”]

As (a student, professor, etc.) in the University of Kansas's Department of \_\_\_\_\_\_\_\_\_\_\_, I (we) am conducting a research project about \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. I would like to (ask you a few survey questions) (interview you) (ask you to be in a focus group) to obtain your views on \_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your participation is expected to take about \_\_\_\_\_minutes. You have no obligation to participate and you may discontinue your involvement at any time.

Your participation should cause no more discomfort than you would experience in your everyday life. Although participation may not benefit you directly, the information obtained from the study will help us gain a better understanding of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your identifiable information will not be shared unless (a) it is required by law or university policy, or (b) you give written permission.

*\*It is possible, however, with internet communications, that through intent or accident someone other than the intended recipient may hear your response.*

*\*\*This interview will be recorded. Recording is (not) required to participate. You may stop taping at any time. The recordings will be transcribed by (me, other investigator). Only (I, the investigator(s), and/or the faculty supervisor) will have access to recordings which will be stored [describe security measures] and will be destroyed in [time frame].*

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

*Example 1:* Your 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 identifiable information and/or biospecimens will not be used or distributed for future research studies even if your identifiable information is removed.

Participation in the (interview) (survey) (focus group) indicates your willingness to take part in this study and that you are at least 18 years old. Should you have any questions about this project or your participation in it you may ask me (us) or my (our) faculty supervisor, \_\_\_\_\_\_\_\_\_\_\_ at the Department (School of) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. If you have any questions about your rights as a research participant, you may call the Human Research Protection Program at (785) 864-7429 or email irb@ku.edu.