Informed Consent Document Template

PROJECT TITLE

INTRODUCTION

You are invited to join a research study to look at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. The decision to join, or not to join, is up to you. In this research study, we are investigating/testing/comparing/evaluating \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*The information here should be a clear and short description of the “bottom line” of the study. Hold details of the study until later in the document. Briefly give the subjects some background information about why this study is being done, this can include information about what is already known and what you hope to learn.*

WHAT IS INVOLVED IN THE STUDY?

If you decide to participate you will be asked to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. We think this will take you \_\_\_\_\_\_\_\_\_\_\_minutes.

*Refer to the subjects as “you.” Tell subjects exactly what to expect. Explain what will happen during the study and how the study will work. Include everything that subjects will be asked to do. Describe all surveys and data collection instruments that subjects will experience. Indicate how long each survey or procedure will take and state how long (e.g. minutes, hours, days, months, until a certain event or endpoint) the subjects will be part of the study.*

The investigators may stop the study or take you out of the study at any time they judge it is in your best interest. They may also remove you from the study for various other reasons. They can do this without your consent. You can stop participating at any time. If you stop you will not lose any benefits.

*If appropriate, list any additional reasons why subjects might be taken off the study.*

RISKS

This study involves the following risks \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. There may also be other risks that we cannot predict.

 *List the physical and non-physical risks of participating in the study above. Non-physical risks may include social, psychological, or economic harm; risk of criminal or civil liability; or damage to financial standing, employability, or reputation. It is also acceptable to say “There are no foreseeable to risks to participation in this study” if that is the case.*

BENEFITS TO TAKING PART IN THE STUDY?

It is reasonable to expect the following benefits from this research: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. However, we can’t guarantee that you will personally experience benefits from participating in this study. Others may benefit in the future from the information we find in this study.

*List all the benefits that might reasonably be expected from participating in the study. First describe benefits to subjects, then describe benefits to others. If there are no benefits from participating in the research, state that fact.*

CONFIDENTIALITY

We will take the following steps to keep information about you confidential, and to protect it from unauthorized disclosure, tampering, or damage: \_\_\_\_\_\_\_\_\_\_\_

*Include such items as anonymity of response, storage of surveys in locked cabinet, destruction of surveys after study completion. List all individuals and agencies who will have access to the data and records, and how data will be described if published or shared with others. Will you be using direct quotes which could be traced to an individual? Will you be aggregating the data?*

Describe confidentiality protections here. Explain how you are protecting the subject’s information. Give details as appropriate: for example, are data files kept in locked cabinets, are the data kept on a computer, is a password required for getting onto the system; who has access to the data, etc.

INCENTIVES

Indicate if subjects will receive anything for participating.

YOUR RIGHTS AS A RESEARCH PARTICIPANT?

Participation in this study is voluntary. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled, and it will not harm your relationship with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*Describe procedures for withdrawing and any follow-up that you will request for subjects who withdraw early. Follow-up such as questionnaires that are part of the research cannot be forced upon subjects who wish to withdraw.*

CONTACTS FOR QUESTIONS OR PROBLEMS?

Call \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or email\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_if you have questions about the study, any problems, unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening. Contact Linda Cook, Chair of the Institutional Review Board, at (405) 208-5904 or lcook@okcu.edu (link sends e-mail) if you have any questions or concerns about your rights as a research participant.

*Provide the name of one or more researchers who can be reached for assistance. If you are a student provide your advisor's contact information too.*

Consent of Subject (or Legally Authorized Representative)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Subject or Representative Date

I have explained the study and the Informed Consent to the research participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Researcher Date

*Upon signing, the subject or the legally authorized representative will receive a copy of this form, and the original will be held in the subject’s research record.*