

## **Park University Consent Form Template**

This template has been developed to assist investigators develop an informed consent document that contains all of the elements of informed consent required by the federal guidelines and additional language required by Park University. The template should be downloaded and modified to meet the specific needs of the study. The sections appear in an order intended to promote understanding of the research participants but sections may be re-ordered as appropriate. Suggested and or required language for sections is printed in lowercase, *guidance is italicized*.

### **Consent for Participation in a Research Study** *[ Project Title]*

*[Name of principal investigators and co-investigators]*

#### **Invitation to Participate**

“You are invited to participate in a research study”

#### **Who will Participate**

*Identify the population eligible to participate as well as the number of participants sought.*

#### **Purpose**

*Include a brief statement which explains the research question and purpose in language that is not technical, and does not use jargon or acronyms, unless they are defined. If the study includes deception, or the withholding of information, this section should be written so that the least possible withholding of information occurs.*

#### **Description of Procedures**

*Describe what will happen to the participant if they decide to participate, detail in a step-by-step manner the activities participants will be asked to engage in, how long it will take, where the research will take place, and how often they will be asked to perform the research tasks.*

### **Voluntary Participation**

*Explain that participation is voluntary, that research participants may choose not to participate at all, or may refuse to participate in certain activities or answer certain questions, or may discontinue participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled. Describe procedures for withdrawing as well as what will happen to any data collected from the participant prior to withdrawal.*

“Participation in this study is voluntary at all times. You may choose to not participate or to withdraw your participation 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.”

“If you decide to leave the study the information you have already provided \_\_\_\_\_.”

### **Fees and Expenses**

*Describe in detail any monetary costs to the participant, if there are any.*

### **Compensation**

*If research participants are to be compensated for participation or reimbursed for expenses, specify the amount, schedule of payment, and conditions for payment. If class points or some other token are to be received by participants include that information here. If compensation is pro-rated when a participant withdraws prior to completing the study, explain how it is pro-rated.*

### **Risks and Inconveniences**

*Tell participants about any risks or discomforts that might occur including psychological, emotional, physical, social, privacy issues, economic harm, risk of criminal or civil liability, damage to financial standing, employability, or reputation etc. If there are no known risks say so.*

### **Benefits**

*List any direct benefits to research participants or others that may be expected from the research. Usually there is only a possibility of benefit or no benefit (state accordingly). Benefits may apply directly to the participant or indirectly to society at large.*

### **Alternatives to Study Participation**

*Disclose appropriate alternative procedures or courses of treatment. If there are no alternatives it may be stated “the alternative is not to participate”. This section can be deleted if it does not impact the information needed for research participants to decide about participation.*

### **Confidentiality**

*Describe the methods to be used to help ensure confidentiality. Explain how the information will be stored, who will have access, and when it will be destroyed. When applicable, explain any foreseeable circumstances, under which the Investigator will be required to give information about the research participant to a third party, such as mandatory reporting of child abuse.*

**Required text:** “While every effort will be made to keep confidential all of the information you complete and share, it cannot be absolutely guaranteed. Individuals from Park University Institutional Review Board (a committee that reviews and approves research studies), Research Protections Program, and Federal regulatory agencies may look at records related to this study for quality improvement and regulatory functions.”

### **In Case of Injury**

*Park University requires formal (but not informal ) consent documentation to include the following paragraphs dealing with Park University’s liability to research subjects.*

**Required text:** “Park University appreciates the participation of people who help it carry out its function of developing knowledge through research. If you have any questions about the study that you are participating in you are encouraged to call **(name)**, the investigator, at **(phone number)**.”

**Required text:** “Although it is not the University’s policy to compensate or provide medical treatment for persons who participate in studies, if you think you have been injured as a result of participating in this study, please call the **(Chair’s name)** of PARK UNIVERSITY’s Social Sciences Institutional Review Board, at **(Chair’s phone number)**.”

### **Questions**

*Provide contact information for researchers including name, address, area code and phone number, and email address.*

### **Authorization**

*Include a line for participant’s printed name, signature of participant and date, investigator’s printed name, signature of investigator and date.*