IRB TEMPLATE
FOR DEVELOPMENT OF THE ADULT CONSENT FORM

SOCIAL SCIENCE AND BEHAVIORAL RESEARCH

The following instructions and examples are provided to assist in development of the Adult Consent Form. All forms should be submitted suitable for reproduction (printed single sided) using a 12 point font and 1 inch margins. Each page of the consent form should be full without inappropriate divisions: sections can be split (some on one page, some on another page) so that large blank areas do not exist. Upon final approval, all pages must include the IRB number in the upper left corner, the page numbers in the upper right corner and a participant's initial blank in the lower right corner.

The following should be considered when developing the consent form:

1. The informed consent form must be written in the second person. When combined with conditional language, utilization of the second person personalizes the consent form and reflects the existence of voluntary decision making on the part of the prospective subject.

2. The informational content of the elements of informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the prospective subject focus on each individual element of consent thereby increasing the validity of the consent process.

3. The consent form must be written in simple enough language so that it is readily understood by the least educated of the subjects to be utilized. Normally the highest level of language in the consent form should equate to an eighth grade standard. Scientific terms should be avoided when possible.

Title of this Research Study

List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.

Invitation

Invite the prospective subject to participate in the study using the following standard invitation to participate:

> You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

Why are you being asked to be in this research study?

Explain succinctly and simplistically why the prospective subject is eligible to participate. As appropriate, major eligibility criteria may be included in this section (eg "You are being asked to be in this study because you are either an employee or a supervisor working a night shift").

What is the reason for doing this research study?

This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential subject understand why the research is being done (eg, "People who work at night employ different strategies for staying awake during their shifts. These methods are likely to be different between employees and supervisors, because of their different levels of responsibility. This research is designed to (1) better understand these strategies and (2) determine whether 'supervisor strategies' could be successfully used by employees.") This information should be provided in simplistic language without reference to the subject.

What will be done during this research study?

Describe the procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of subheadings helps to organize this section and increases readability.

What are the possible risks of being in this research study?

Identify each intervention with a subheading and then state the associated risk(s) using simplistic language (section II.12 of application). The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress.

Alternately, if there are no known risks use this standard clause:

> There are no known risks to you from being in this research study.

What are the possible benefits to you?

If direct subject benefits can reasonably be anticipated as a result of participating in the protocol (section II.15 of application), then describe these possible benefits. Conclude with the following standard clause:

However, you may not get any benefit from being in this research study.

If direct subject benefits are NOT anticipated, then use the following standard clause:

You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?

State the possible benefits to society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective subjects' position (section II.16 of application).

What are the alternatives to being in this research study?

Describe, in reasonable detail, alternatives the prospective subject may have available (section II.17 of the application). Alternately, use the following standard clause if applicable:

Instead of being in this research study you can choose not to participate.

What will being in this research study cost you?

This section should state the financial obligations the subject will incur as a result of participating in the study (section II.19 of the application). If there are no financial obligations to the subject then use the following standard clause:

There is no cost to you to be in this research study.

Will you be paid for being in this research study?

If the subject will receive compensation for participating in the research, state the amount of compensation and conditions for payment (section II.20 of application). A prorated payment system should be used when appropriate. If no compensation is provided, then use the following standard clause:

You will not be paid to be in this research study.

What should you do if you have a problem during this research study?

Your estimation of risk determines what additional information you will include in this section (section II.13 of application).

For studies classified as minimal risk, use the following standard clause:

> Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

For studies classified as greater than minimal risk, use the following standard clause.

> If you have a problem or experience harm as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form. Agreeing to this does not mean you have given up any of your legal rights.

How will information about you be protected?

Begin with the following standard clause:

> Reasonable steps will be taken to protect your privacy and the confidentiality of your study data.

Next, if the research requires collection of sensitive information (socially, financially, legally or otherwise) from the prospective subject, follow the introductory standard clause (above) with a brief description of the precautions which will be utilized to protect that data (section 10.b of application).

Finally, for all protocols, conclude with the following standard clause:

> The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law. The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential

What are your rights as a research subject?

Use the following standard clause:

You have rights as a research subject. These rights have been explained in this consent form and in *The Rights of Research Subjects* that you have been given. If you have any questions concerning your rights or complaints about the research, talk to the investigator or contact the Institutional Review Board (IRB) by:

- telephone (256) 726-7048
- Email: pcook@oakwood.edu
- Mail: IRB Oakwood University, 7000 Adventist Blvd. NW. Huntsville, Alabama 35896

What will happen if you decide not to be in this research study or decide to stop participating once you start?

Use the following standard clause:

You can decide not to be in this research study, or you can stop being in this research study ("withdraw") at any time before, during, or after the research begins. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator, or with

Oakwood University
[OR]
any other entity connected with Oakwood University.

You will not lose any benefits to which you are entitled.

If the research team gets any new information during this research study that may affect whether you would want to continue being in the study you will be informed promptly.

Documentation of informed consent

Use the following standard clause:

You are freely making a decision whether to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to be in the research study.

If you have any questions during the study, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

_ Signature of _Subject_____

Date:_____ Time_____

For all studies include the following investigator certification clause:

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person Obtaining Consent: Date:

Authorized Study Personnel

List by name those personnel authorized to document consent as listed in the IRB Application. Use the following subheadings: Principal Investigator, Secondary Investigator(s), and Participating Personnel. Include day phone numbers for all listed individuals. For greater than minimal risk studies, include night/home phone numbers and/or other direct contact mechanism. List other study personnel and contact information as appropriate.