

# THE CONSENT PROCESS

## Consent Form Template

**Following is a format that addresses the elements of informed consent and may be used as a reference when preparing this document.**

[DEPARTMENTAL LETTERHEAD]

### Consent Form

[Project Title]

[Name of principal investigator and co-investigators]

[Note 1: The sections below appear in an order that promotes subject understanding, but sections may be re-ordered as appropriate.]

[Note 2: Starred (\*) sections may be deleted if they do not apply, however, the IRB may require that they be included.]

### **Introduction**

This part of the consent form must state that this is a research study and it should indicate why the person is being asked to participate. It should state which department is conducting this study. It should say that subjects should read the form carefully and instruct them to ask the investigator and/or person obtaining consent any questions that they may have before making a decision whether or not to participate. Especially for long-term studies, complex procedures and studies with greater risk, this section should emphasize that the form contains important information and that subjects should keep their copies to refer to as the study proceeds.

The introduction is an opportunity to reinforce the voluntary nature of subjects' participation ("You are being asked to participate ..." "You are invited to participate...") The introduction may be used to provide background on why the study is being conducted and its importance and the importance of subject participation. The importance, however, should not be overstated or exaggerated.

### **Purpose of Study**

This section of the consent document must, briefly and simply, inform the subject of the purpose (aim/goal) of this study. It may be appropriate to inform the subjects if the study is being undertaken just locally or on a larger scale, e.g., citywide, regionally, nationally, or internationally.

### **Description of Study Procedures**

This section should contain a complete description of the procedures that are necessary to complete the study. All experimental procedures must be described and any related but non-experimental procedures should be stated. The subject's time commitment must be explained in terms of the length of study, visits required and any other activities (e.g., diaries, telephone follow-up) required for completion. Use listings, tables and charts to show complex schedules and study designs.

For medical studies this section would include explanations about medications being given, the amount of blood drawn, invasive and/or non invasive procedures, length of hospital stay, follow-up procedures and the like.

- All scientific/medical/technical terms should be defined or explained in lay terms.
- Avoid the use of undefined medical abbreviations such as EKG, U/A, SMA-12.
- If the study involves a randomization, then the randomization procedure should be explained along with the chances of receiving each of the options.
- If the study involves the use of a placebo, define placebo.
- If the study is double/single masked, explain the meaning for the subject.
- If there are explicit exclusion or inclusion criteria for the study, e.g., allergies, pregnancy, medical conditions, use of certain medications, etc. they can be included in this section. [Note: the risk of pregnancy is not an acceptable criterion to exclude women of childbearing potential! Contraceptive measures and pregnancy testing can be used, with removal from the study if positive.]
- Use tables and/or charts to show complex schedules.

### **Risks of Participation**

This section should contain a sufficient description of the risks to enable subjects to decide if they want to participate. Information on probability of the risks and the magnitude and reversibility of harmful effects is helpful to this process. List any:

- Potential behavioral and psychological risks such as triggering bad memories, learning disturbing things about one's self, nervousness about being observed, etc. need to be delineated.
- Legal and social risks, if any, need to be stated as well as risks to confidentiality or privacy.
- Specific risks to confidentiality and or privacy (see also below).
- Side effects for each drug, device or procedure. Specify if side effects are reversible and/or treatable, and what monitoring will occur to detect/control side effects. Indicate that all drugs have side effects. If appropriate, you may state that the subjects may experience all, some or none of the side effects listed.
- For drug studies, this section may point out that there is always the risk of previously unknown side effects occurring.
- It may be useful to instruct subjects to report any side effects.
- If the study involves blood draws, mention that this might cause pain and bruising at the site where the blood is taken, and sometimes, that it causes people to feel lightheaded or even to faint.
- If a sample consent form has been provided by a study sponsor/group, all the risks from the sample consent must be included in the USC consent form.

**Number of Participants \***

This is actually an additional 'risk' consideration. If the total number of subjects to be studied is important to consider before entering the study (e.g., if a small number of subjects may compromise confidentiality by making it easy to identify who the subjects are or for the first 'phase 1' study of a new drug where only a few subjects are permitted to be exposed), the expected numbers should be stated. (This statement may also be placed in the Risk section above.)

**Benefits of Participation**

List any direct benefits to the subject or to others that reasonably may be expected from the research. Usually there is only a possibility of benefit or no benefit (so state). Benefits to others would include possible development of commercial products. It may be permissible to state that a project may yield results that could possibly benefit a sub-population (e.g., AIDS patients, low birth weight babies, students and so forth).

**New Study Findings \***

New findings developed during the course of the research may change subjects' willingness to continue to participate. If so, subjects need to be informed that these findings will be provided to them. This may require new consent forms or addenda.

**Alternatives \***

Disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. Usually, medical studies have alternatives, e.g., 'standard' treatment, no treatment, other research studies, etc. If a test drug/device is available "off protocol" (i.e., approved for use) that needs to be stated. Other types of studies may have alternative actions such as other options to earn course credit (e.g., reports and papers) or availability of non-research services.

For minimal risk studies that have no alternatives (e.g., some survey research), it may be stated that "the alternative is not to participate" or you may delete this section if it does not impact the information needed to decide about participation.

**Costs \***

Any additional costs that may result from participation in the study must be listed. The following are examples of acceptable wording:

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

[or for medical studies]

How much you will have to pay depends on whether or not you have insurance and what costs your insurance will cover. You or your insurance carrier will be responsible for the costs of clinic visits, any hospital admissions, laboratory tests, x-rays, and other tests. Insurance coverage cannot be guaranteed for tests and treatments related to this study.

**Payments \***

If subjects are to be paid for participation or reimbursed for expenses, specify the amount, schedule of payment, and conditions for payment. Payment should be based on a prorated system. This means that payments are earned/given as the study progresses and that subjects do not have to complete the entire study to receive a payment. [Note: For clarity, do not use the word "compensation" to refer to incentive payments or reimbursements for expenses (see Compensation for Injury below).] Note too, that advertisements may mention, but must not emphasize payments and all advertisements must first be approved by the IRB. If medications, tests and therapies are to be provided free as part of the study, specify.

**Circumstances for Dismissal from the Study \***

List the circumstances, if any, under which the subject's participation may be terminated without his/her consent. The following are examples of acceptable wording:

- If you do not keep appointments for study visits or fail to complete study activities, e.g. taking study medications or completing forms.
- If you do not follow the instructions you are given. Note: do not use the phrase "fail to follow the protocol or research procedures" as subjects do not have this information.
- If your disease becomes worse or if your doctor feels that staying in the study is harmful to your health. Further treatment would be discussed at that time.
- If new scientific developments occur that indicate the study is not in your best interest.
- If the study sponsor decides to stop or cancel the study.

#### **Compensation for Injury \***

There should be a statement regarding responsibility for payment of emergency medical care related to the study. In most cases, sponsors are willing to pay for costs incurred for treatment of injury or illness directly related to the study. If partial or no compensation is available, it should be clearly stated.

#### **Confidentiality of Records**

There should be a statement regarding confidentiality of research data and records. The following is an example of acceptable language.

While we will make every effort to maintain confidentiality, it cannot be absolutely guaranteed. Records that identify you and the consent form signed by you may be inspected by a regulatory agency (FDA, NIH etc.) and/or the University's Institutional Review Board. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed.

#### **Contact Persons**

The consent form must address three (3) areas for subjects' questions, namely, questions about the research itself, questions about research related injury and questions about subject's' rights. Examples of acceptable wording for this section:

For more information concerning this research you should contact [specify name] at [telephone number]. [Note: this person is usually the PI]

If you believe that you may have suffered a research related injury, contact: [specify name] at [telephone number] who will give you further instructions. [Note: this person is usually the PI or, if the PI is not a physician, some pre-arranged medical contact.]

If you have any questions about your rights as a research subject, you may contact:

Thomas Coggins  
Office of Research Compliance  
University of South Carolina  
Columbia, SC 29208 Phone – (803) 777-7095

#### **Voluntary Participation**

Recommended wording for this section:

Participation in this study is voluntary. You are free not to participate or to withdraw at any time, for whatever reason. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

For medical studies, state that the subject does not risk loss of present or future care they would otherwise receive.

For studies with students, state that the subject does not jeopardize grades nor risk loss of present or future faculty/school/University relationships.

### **Signatures /Dates**

The signature of the subject and/or subject's legal representative indicates an agreement to participate. The date (which should be in the subject's writing) is meant to indicate that consent was obtained prior to the subject being involved in any research procedures. With few exceptions, the subject's signature and date of signature are required by the federal regulations for human research subject protection and the University of South Carolina's research policy. The signature of the subject's legal representative indicates permission to participate is granted by a person legally empowered to give consent to research.

The signature of the person obtaining consent indicates that the form has been read by or read to the subject; an appropriate explanation of the research was given; questions from the subject were solicited and answered to the subject's satisfaction; and, in this person's judgment, the subject demonstrated comprehension of the information. While this signature is not required by federal regulations, the University of South Carolina does strongly encourage this signature for all research that presents greater than a minimal risk to subjects. The date of signature should also be recorded when this signature line is used.

The signature of a witness attests to the fact that the form was read by or read to the subject, that an explanation of the research was given, that questions from the subject were solicited and answered to the subject's satisfaction, and that, in this person's judgment, the subject voluntarily agreed to participate. This signature is not required by federal regulations. However, the IRB may require this signature for some research that presents greater than a minimal risk to subjects. This is both to protect the subjects and the investigators. The date of signature should also be recorded when this signature line is used.

For studies with minors (children under age 18), two forms may be used (an 'assent' with the child's signature line and a 'permission form' with the parent's signature line) or, if appropriate, one form with both signature lines.

Recommended wording for this section:

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form for my records and future reference.