

Guidelines on Informed Consent Park University Institutional Review Board

With very few exceptions research protocols must include a consent process providing the opportunity for potential research participants to make a fully informed decision whether or not to participate in the research. Informed consent is one of the basic ethical obligations for researchers.

Informed consent is a process not a form

Informed consent is a term which describes the communication process that enables individuals to make an informed choice about participation in a research study. Consent is an ongoing process which starts well before any forms are signed and continues until the research subject's participation is complete.

The informed consent process includes the discussion which takes place between the investigator and the research participants and the written document that formalizes the agreement to participate and documents the process.

For consent to be informed, the research participants must fully understand the study. Therefore information must be conveyed in a manner to enhance understanding rather than to just provide disclosure.

What needs to be said about the research

Although each research study is unique, the federal regulations for human research and the Institutional Review Board (IRB) identify basic elements of informed consent [(45 CFR 46.116(a)&(b))] which are required to be contained in all consent forms:

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. a description of any reasonably foreseeable risks or discomforts to the subject;
3. a description of any benefits to the subject or to others which may reasonably be expected from the research;
4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Federal regulations and the IRB require several other elements of information to be included if they apply to the study and are important for participants to know. These include:

1. a statement that particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. any additional costs to the subject that may result from participation in the research;
4. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. the approximate number of subjects involved in the study.

What needs to be said about the conduct of the research

1. Confidentiality

The level of confidentiality of the research data and the measures that will be taken to ensure that confidentiality should be described by the investigator. Special attention should be given to the limits of confidentiality such as the legal duty to report abuse that might supersede confidentiality. Also the investigator must provide notification that the

IRB, the sponsor of the study or university and government officials responsible for monitoring the study may inspect study records.

2. Conflict of Interest/ Financial Interest

In order to deal with financial conflicts of interest and potential financial conflicts of interest and to ensure objectivity in research, Park University has in place a conflict of interest policy. The conflict of interest policy states that: University employees shall faithfully discharge their duties and shall refrain from knowingly engaging in any outside matters of financial interest incompatible with the impartial, objective and effective performance of their duties. They shall not realize personal gain in any form, which would influence improperly the conduct of their university duties. They shall not knowingly use university property, funds, position or power for personal or political gain. They shall inform their supervisor in writing of reasonable foreseen potential conflicts.

3. Payments to research participants

If subjects will be compensated for participating in a study, the consent form must describe the terms of payment and the conditions under which partial or no payment would be received. The effects of withdrawal from the study before participation is completed should be explained in detail.

Documenting the research participant's consent with a consent form

1. Language used in consent forms and or information sheets must be understandable to the research participant, therefore:

- It should be written at no higher than an 8th grade reading level
- Use short sentences and non-technical terms
- The second person should be used since the first person can be interpreted as suggestive (the second person pronoun e.g., “you are being asked to participate in a study because...” is preferred because it is inherently more open and conversational with subjects).
- Do not use qualifying phrases such as “you understand that”, substitute wording such as “you have been told” or “it has been explained to you” etc.
- Avoid language which may appear to waive any rights to which the research participant is entitled.
- All scientific, medical and technical terms should be defined or explained
- If children are involved and are between 10 and 17 years of age, provide for parental permission and assent of child.
- For younger children provide for parental permission and on the child assent form add a sentence stating that the study has been discussed with them and they agree to participate.

- If persons are involved who are unable to give informed consent, provide for consent from a legally authorized individual and provide an assent form to be read by or read to the research participant.
- For non-English speaking people provide translated versions (Describe the translation process which must include a back translation, and identify the qualifications of the individuals completing the translations.).
- Check spelling and grammar.

2. Format and specific requirements include the following:

- Make sure there is at least a 1” margin on all sides.
- Do not use a font smaller than size 12.
- Consent forms must be typewritten.
- Use headings and “white-space” to improve readability in long forms.
- Number pages page x of y on each page.
- Include footer with current version date on each page. This date should be updated each time a new version of the consent form is approved by the IRB.

3. IRB approval and expiration dates will be stamped on each page of the consent form by the IRB office following approval.

Copies of the current, dated documents are the only versions that may be used by investigators when obtaining consent. Therefore the investigator should make copies of the stamped version returned to them by the IRB at the time of study approval or re-approval. This procedure is designed to assist the investigator in assuring that only the current, IRB-approved informed consent documents are presented to research participants. The stamp also provides a reminder to Investigators of the need for continuing review.

4. The use of Video and Audiotaping should be clearly stated in the consent form and the following information should be included:

- How the recordings will be used.
- How long the recordings will be kept.
- Who will see/hear the recording and where it will be used.
- If permission is sought for the recording to be viewed or heard by anyone other than the research staff, or if it involves sensitive material, then the opportunity should be given to research participants to view, or listen to the recording after it is completed. Permission for the tape to be used should then be obtained.
- Who will transcribe the tapes, and if third-party transcriptionists will be used include steps that will be taken to protect confidentiality.

5. Recordkeeping practices with regard to informed consent should include:

- Giving each subject a complete copy of the consent form.
- The investigator is required to keep signed consent forms on file for 3 years following the completion of the research.

6. Anonymous and Confidential Data must be clearly identified in the consent form.

Promises of anonymity should not be made to subjects unless the research data is truly anonymous. Anonymity can only be promised if there is no method by which anyone including the investigator can connect the research results with individual research participants providing the data. The existence of codes or master lists that enable the investigator to identify research participants prohibits anonymity from being possible even though the research participants names may not appear in the data set. In this instance the data would be considered confidential rather than anonymous.

When to submit the form to the IRB

Investigators must submit consent forms when they first apply for IRB review and approval, and when they apply for continuing review. Because the requirements for consent forms change over time, due in part to changes in regulatory mandates, the IRB reviews the form at renewal to ensure that it is consistent with current requirements. In addition the IRB may ask investigators to revise consent forms at other times, when circumstances warrant. Any revisions made to a previously approved consent form must be submitted to the IRB for approval BEFORE use.

Assent

In the State of Missouri only individuals 18 years or older may legally consent to participate in research. This legal authority may be withheld for some groups of individuals with limited decision-making or cognitive ability. In addition, some individuals voluntarily give this authority to another through a power of attorney or other legal instruments.

Individuals who do not have the authority to consent to participate in research must still provide their agreement. "Assent" is defined as an affirmative agreement to participate and differs from "consent" which can only be given from a person with the legal authority to do so.

An assent process is therefore used when an investigator recruits research participants who, by age or circumstance, are not able to give legally effective consent. Even very young children or those with limited decision making or cognitive ability can indicate a desire not to participate which should be honored even when the parent or legally

authorized representative gives permission unless the research is taking place in a therapeutic setting.

The child or person with limited decision making ability documents their agreement with an “Assent Form” which outlines the essential information about the study. Both the assent discussion with the subject and the assent form should use language especially designed for the group of individuals with whom it will be used. The form should include the following information:

- Explain why the research is being conducted;
- Describe what will happen and for how long or how often;
- Say agreeing to participate is up to the person who is being invited to participate and it is okay to say no;
- Explain if it will hurt and if so for how long and how often;
- Say what the other choices are;
- Describe any good things that might happen;
- Describe any bad things that might happen;
- Say whether there is any compensation for participating; and
- Ask for questions.

Written permission from parents or guardians is required for research involving children or persons with limited decision making. This permission is typically documented in a form similar to a consent form. Under some limited circumstances a “waiver of parental consent” can be granted by the IRB. Such waivers are only granted after review by a convened meeting of the board.

Waiver or Alteration of Informed Consent

There are two types of waivers or alterations which may be presented to the IRB:

1. Waiver or alteration of the **PROCESS** of obtaining informed consent can be obtained under certain circumstances. In this instance the investigator would not obtain informed consent from the participant and there would not be an informed consent document reviewed and approved by the IRB. The research however must meet certain conditions in order for such a waiver to be granted. These conditions are outlined below.

- An example of such a condition might be if an investigator wishes to review and record existing identifiable information from a dataset for the purpose of analysis. The information might have been recorded several years ago and therefore the likelihood of being able to contact participants is not practicable. If the information to be recorded would not place research participants at risk should there be a breach of confidentiality it is possible that this type of research may meet the acceptable conditions in which a waiver may be granted.

2. Waiver or alteration of the **DOCUMENTATION** of informed consent can also be obtained under certain circumstances. In this instance the investigator obtains informed consent however a signature is not obtained. Again, there are specific conditions which must be met which are described below.

- An example of such a condition might be if an investigator wanted to conduct an interview by telephone in order to determine the participant's satisfaction with a new service available currently. A script containing all of the required elements of informed consent would be required for review and approval however no signature would need to be obtained.

Waiver or Alteration of the Consent Process

Under certain circumstances the Federal regulations give the IRB the authority to waive or alter the required informed consent process (§46.116)

Waiver for Research Activities Designed to Study Certain Aspects of Public Benefit or Service Programs

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirement to obtain informed consent entirely provided the IRB finds and documents that:

- The research or demonstration project is to be conducted by or subject to the approval of State or local government officials and is designed to study, evaluate, or otherwise examine:
 1. public benefit or service programs;
 2. procedures for obtaining benefits or services under those programs;
 3. possible changes in or alternatives to those programs or procedures; or
 4. possible changes in methods or levels of payment for benefits or services under those programs; AND
- the research could not practicably be carried out without the waiver or alteration.

Waiver for Minimal Risk Studies

The IRB may also approve a consent procedure which does not include, or which modifies, some or all of the elements of informed consent, or waive the requirement to obtain informed consent entirely provided the IRB finds and documents that:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;

- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Documentation of Consent Process

Under limited circumstances, the IRB may approve procedures which waive the requirement of a signed written consent document. The IRB must find either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or

NOTE: *If this requirement is waived by the IRB under this condition then each research participant must be asked whether they want documentation linking them with the research, and their preference shall govern.*

- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

When the documentation requirement is waived, the IRB may require the investigator to provide written information statements regarding the research. This information sheet or letter should include the majority of the information that would be found in a consent form without the PARK UNIVERSITY Disclaimer Statement and Signature Lines.

Certificates of Confidentiality

When additional protections are needed for the collection of sensitive data, the IRB may request or the Investigator may choose to obtain a Certificate of Confidentiality. The existence of such a certificate should be described in the informed consent document. For more information regarding this issue, see the excerpt below from the OHRP Guidance Document “Certificates of Confidentiality 2/25/2003”

Certificates of confidentiality are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information from forced or compelled disclosure. They allow the Investigator and others who have access to research records to refuse to disclose identifying information on research participants in civil, criminal, administrative, legislative, or other proceedings, whether Federal, State, or local. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for participants, such as damage to their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help to minimize risks to participants

by adding an additional level of protection for maintaining confidentiality of private information.

For more information on Certificates of Confidentiality and their use see

<http://grants2.nih.gov/grants/policy/coc>

Consent and Language Barriers

When research will include non-English speaking participants, researchers should prepare both English-language and translated consent/assent forms. An explanation for the translation process and the expertise of the translator as well as a **“back-translation”** should be provided to the SSIRB. A back-translation process consists of the following steps : (1) the consent form written in English is translated into the subject’s language (2) The version in the subject’s language is translated back into English by someone unfamiliar with the original translation (3) the two English versions are compared for accuracy. This process requires the use of two translators.