Informed Consent Checklist - Basic and Additional Elements

*Note: To be used to assist investigators in writing consent documents and/or scripts.

**Basic Elements**

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- 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
- An explanation of whom to contact for answers regarding the following:
  
  **a) answers to pertinent questions about the research and research subjects' rights**
  “If you should have any questions about this research project, please feel free to contact (name of researcher) at (researcher’s phone number) or my Faculty Advisor, (name of advisor), at (advisor’s phone number)”

  **b) answers to pertinent questions about subjects’ rights**
  “For additional information regarding human participation in research, please feel free to contact the UMR Campus IRB Office at (573) 341-4305.”

  **c) whom to contact in the event of a research-related injury to the subject**
  “It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri does have medical, professional and general liability self-insurance coverage for any injury caused by the negligence of its faculty and staff. Within the limitations of the laws of the State of Missouri, the University of Missouri will also provide facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participating in this research program, you are to contact [e.g. the Risk Management Officer at (573) 882-3735 who can review the matter and provide further information. This statement is not to be construed as an admission of liability.]”
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.

**Additional elements, as appropriate**

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A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

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Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent

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Any additional costs to the subject that may result from participation in the research

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The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject

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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

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The approximate number of subjects involved in the study

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§46.117 Documentation of Informed Consent Checklist

a. Except as provided in paragraph “c” of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject’s legally authorized representative. **A copy shall be given to the person signing the form.**

The consent form may be either of the following:

**WRITTEN**

A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject’s legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

**DONE ORALLY**

“A short form written consent document, stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.”
WAIVER of req't for signed form

" c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:
1. 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Additional Assistance

45 CFR 46 - Protection of Human Subjects:
http://grants.nih.gov/grants/oprr/humansubjects/45cfr46.htm

OPRR Informed Consent Checklist:

OPRR Informed Consent Tips:

Informed Consent - Non-English Speakers:

Informed Consent - Legally Effective and Prospectively Obtained:
http://grants.nih.gov/grants/oprr/humansubjects/guidance/hsdc93-03.htm

What is informed consent? – U.S. Department of Energy, Human Subjects Office:

*Note: The Informed Consent Checklist located on the homepage of OPRR Human Subject Protections (listed above) was used as a guide in the development of this form. UMRIRB-3