Office for Human Research Protections (OHRP)

§46.116 Informed Consent Checklist – Basic and Additional Elements

- x A statement that the study involves research
- x An explanation of the purposes of the research
- x The expected duration of the subject's participation
- x A description of the procedures to be followed
- x Identification of any procedures which are experimental
- x A description of any reasonably foreseeable risks or discomforts to the subject
- x A description of any benefits to the subject or to others which may reasonably be expected from the research
- x A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- x A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- x 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
- x Research, Rights or Injury: 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
- x A statement that participation is voluntary, refusal to participate will involve no penalty

§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.

Written
The consent form may be either of the following:

1. 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

2. 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 Requirement for Signed Form , butf -0.003 T(F)8.303(-T(F)8.3(d)-at4rm

§ 46.116 - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

x

appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.