Guidance and Instructions for Documentation of Informed Consent

Informed consent shall be documented (unless exempted by IRB) by the use of a written consent form approved by the IRB and signed and dated by the subject and/or the subject's legally authorized representative (surrogate consent) at the time of consent**.** The signature of the person explaining the research and date shall also be documented on the consent forms at the time of consent. A copy shall be given to the subject and/or the subject's legally authorized representative signing the form. A copy of all information given to the subject, including consent forms, shall be retained in the medical record or research file.

At the discretion of the PI, a "short form" consent may be used for subjects with language, hearing, sight or other barriers to understanding stating that the elements of informed consent were presented orally to the subject or the subject's legally authorized representative if a witness is present to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or their representative. The witness shall sign both the short form and a copy of the summary. The person obtaining the consent shall sign a copy of the summary and document that the protocol was presented in a manner/language appropriate to the subject. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

Age for consent:

Subjects the age of eighteen (18) years and older must sign a consent form.
Subjects the age of fourteen (14) years through 17 years may sign a consent form; however, the parent or legal guardian must also sign a permission form.
Subjects the age of seven (7) years through 13 will be presented a verbal or written description (assent) of the research plan. The PI will document that the plan has been presented and that the child has agreed. The child does not sign the assent.

The PI may at his/her discretion decide to use developmental age rather than chronological age and will document this on the consent-assent/permission form.

INFORMED CONSENT

Informed consent will be obtained in a manner and method that meets the requirements of 45 CFR 46.117 and Subpart D, 46.401 – 409.

Parental Permission – Children under 18 years of age must have the permission of their parent/legal guardian to participate in a research project (exception will be if the child is an emancipated minor or a mentally incompetent patient). The permission of one parent is sufficient when the research to be conducted does not involve greater than minimal risk (46.404) or the research involves greater than minimal risk but presents the prospect of direct benefit to the individual child (46.405).

Both parents must give their permission if the research involves greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition (46.406) or the research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (46.407). Exceptions include one parent is deceased, unknown, incompetent, not reasonably available, or when one parent has legal responsibility for the care and custody of the child.

The consent must be in writing and must include the signature and date of the person explaining the research.

Participant's Consent - Children 14 years of age and older must give written informed consent to participate in a research project (the exception will be a child/adult who is mentally incompetent). The information must be presented at a level of understanding depending upon their age, maturity and psychological state. The consent must be in writing for participants over 17 years of age and must include the signature and date of the person explaining the research.

Participant's Assent – Children age 7 through 13 should give assent to participation in the research project. The information should be provided on the same level of the child's ability to understand. Such assent should be documented in the patient's file.

Explanation to Participant – Children under the age of 7 will have the research project explained to them on the same level as the child's ability to understand. Such conversation should be documented in the patient's medical record. If the child objects strongly, re-evaluate the project with the parents.

Reference: Code of Federal Regulations: 45 CFR 46
Protection of Human Subjects, Department of Health and Human Services
National Institute of Health, Office of Protection from Research Risks