Appendix F

Vulnerable Subjects Guidelines

Vulnerable Subjects Guidelines

The general requirements for obtaining informed consent, the elements to be included, and the provisions for waivers all apply to research involving vulnerable subjects including children, pregnant women and fetuses/unborn children, prisoners and persons with mental disabilities. The process of obtaining informed consent for vulnerable populations is complicated by issues such as age, ability to understand and the relationships with parents or guardians.

For research involving children under 18 years of age, investigators must obtain written consent from at least one parent or guardian for participation of each child in the project. If the project involves more than minimal risk, signatures of both custodial parents and guardians will be required.

From about middle school onward, children can comprehend a consent form. Therefore, a written consent from the child (in addition to written parental consent) becomes appropriate. The consent explanation should be worded to match the ability of the participant to understand his or her involvement in the proposed project. A script copy of the explanation to be given should be provided to the IRB.