INFORMED CONSENT - ASSENT

SOP #:	**704**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**5/1/09**	**SUPERSEDES DOCUMENT:**	**/ /**
THIS POLICY PERTAINS TO:			**ALL RESEARCH SUBMITTED TO THE IRB**				
RESPONSIBILITY FOR EXECUTING POLICY:			**ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB MEMBERS**				
LAST REVIEWED ON:		**/ /**		**RESULTS:**	**REVISED**		
APPROVAL AUTHORITY:			**Associate Vice President for Research and Economic Development**				
APPROVED BY:						**DATE:**	**/ /**

1. POLICY

The principle of respect for persons requires that the choice of an autonomous person be respected. This is usually accomplished by soliciting the informed consent of the prospective research subject. In the case of the cognitively impaired adult or non-autonomous child, applying the principle of respect for persons is problematic. However, any individual capable of some degree of understanding (generally, a child of seven or older, or a cognitively impaired adult) should participate in research only if they assent. When assent is required by the IRB, however, the decision of the individual assenting is binding.

2. SPECIFIC POLICIES

2.1 Use of Assent

In instances where the subject is not legally capable of giving informed consent (*e.g.*, children) or where the subject is cognitively impaired, the IRB must find that adequate provisions are made for soliciting the assent of the subject when, in the judgment of the IRB, the subject is capable of providing assent.

2.1.1 Assent means a subject's affirmative agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as assent.

2.1.2 In determining whether subjects are capable of assenting, the Investigator and the IRB shall take into account the age, maturity, and psychological state of the subject involved. This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the subjects is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the subject and is available only in the context of the research, the assent of the subject is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116.

2.1.3 When the IRB determines that assent is required; it shall also determine whether and how assent must be documented.

3. RESPONSIBILITY

The IRB Chairperson and/or IRB member is responsible for determining whether assent is indicated and for follow-up with Investigators, as appropriate.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Subpart D

5. ATTACHMENTS

IC 704-A Informed Consent Document Template: Assent-Non Medical

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Members	Review assent and confirm that language level and content are appropriate.