

	SOP: Assent		
	Number	Approved by	Effective date
	SOP 703	Executive Director, IRB Office, Brigham Young University	1/1/1900
			Page 1 of 2

1. OBJECTIVE

The principle of respect for persons requires that the choice of an autonomous person be respected. Under the usual conditions of clinical research, this is 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. Therefore, consent of either the parent or legally authorized representative is required. 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 should be binding.

Specific Procedures

1.1 Use of Assent

In instances where the subject is not legally capable of giving informed consent (e.g., minors) 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.

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

1.1.2 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.

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



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Number	Approved by	Effective date	Page
SOP 703	Executive Director, IRB Office, Brigham Young University	1/1/1900	Page 2 of 2

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.116 45 CFR 46 Subpart D

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.