

DEPARTMENT: INSTITUTIONAL REVIEW BOARD  
POLICY NUMBER: 038  
SECTION: INFORMED CONSENT PROCESS  
REVIEW RESPONSIBILITY: IRB  
EFFECTIVE DATE: AUGUST 13, 2003  
REVISION DATE:  
LAW IMPLEMENTED: 45 CFR 46.116, 46.117, and 46.402

SUBJECT: Assent of Subjects

1. Whenever a subject is not legally capable of giving informed consent (such as a minor child) 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. "Assent" means a subject's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as an assent.
3. In determining whether subjects are capable of assenting, 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.
4. If the IRB determines that assent is required, it shall also make a determination as to whether and how the assent must be documented.