

The Carle Foundation IRB Policy 703

Subject	Assent		
Approval	Dec 2006	Review	Jun 2009
Revision	Jun 2009		
Scope	These policies and procedures apply to all research under the jurisdiction of the Carle IRB.		
Purpose	To provide guidance in obtaining and documenting assent of children in research.		

Statement of Policy

- For subjects who are minor, consent of the parent, guardian 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. A parent, guardian or legally authorized representative may not force a subject to participate in the research if the subject has affirmatively expressed a desire not to participate. When assent is required by the Carle IRB, however, the decision of the individual assenting should be binding.

Specific Policies

- 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 Carle IRB must find that adequate provisions are made for soliciting the assent of the subject when in the judgment of the Carle IRB, the subject is capable of providing assent.
 - Assent means a subject's affirmative agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as assent.
 - In determining whether subjects are capable of assenting, the Investigator and the Carle IRB shall take into account the age, maturity, and psychological and emotional 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 Carle IRB deems appropriate. If the Carle 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 Carle 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 as stated in IRB Informed Consent Policy 702 Waiver of Informed Consent or Waiver of Documentation of Informed Consent.
 - When the Carle IRB determines that assent is required, it shall also determine whether and how the assent must be documented.

Reference

45 CFR 46.111, 45 CFR 46.116, 45 CFR 46.117, and 45 CFR 46.408

Approval On File

Gopal Kulkarni, PhD
Director of Human Subject Protection

Anna Keck, PhD
Executive Director of the Research Institute

William Schuh, MD, PhD
Medical Director of the Research Institute

Carle IRB Contact:
Carle Foundation Hospital
Carle Institutional Review Board
611 West Park Street
Broadway Research Center (BWRC)
Urbana, IL 61801
Phone: 217-383-4366
Fax: 217-383-3993
Email: irb@carle.com
Web: www.carleconnect.com/irb.shtml