

Issuing Department: Human Subjects Protection Program
Policy Number: 2011-008.3
Policy Title: Informed Consent - Assent

Purpose

The purpose of this policy is to set forth information about obtaining assent from individuals who are either not of age to provide consent or who do not have the capacity to provide consent.

Definitions

See 2011-007.0 for definitions of the following:

Assent	Informed Consent	Legally Authorized Representative	Parent
Permission	Vulnerable Populations - Children		

Policy

Adequate provisions should be made for soliciting the independent, non-coerced assent from children or decisionally impaired persons who are capable of a knowledgeable agreement. In cases where assent is obtained from a child or decisionally impaired subject, permission must also be obtained from parents or legally authorized representatives.

If the person from whom assent is sought refuses, the person should not be enrolled, even if the parents or legally authorized representatives give permission. The Institutional Review Board (IRB) may make an exception to this in studies related to life-threatening illnesses when eligible subjects may benefit from research treatment protocols. Alternatively, if the person from whom assent is sought agrees to participate, the person may not be enrolled if the parents or legally authorized representatives do not give permission. In rare circumstances, depending on the nature of the study and the age and circumstances of the child or impaired adult, the IRB may waive the requirement for permission from parents or legally authorized representatives.

Policy 2011-006.3 addresses in detail issues of assent from children and permission from parents.

The provisions for obtaining the assent of an adult with impaired decision making ability are based on provisions set forth in regulations for obtaining assent of a child. The IRB shall determine that adequate provisions are made for soliciting the assent of the decisionally impaired individual, when in the judgment of the IRB the individuals are capable of providing assent. In determining whether the individuals are capable of assenting, the IRB shall take into account the maturity and psychological state of the individual involved. This judgment may be made for all individuals to be involved in research under a particular protocol, or for each individual, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the individuals 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 individual and is available only in the context of the research, the assent of the individual 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 circumstance in which consent may be waived in accord with 45 CFR 46. For FDA regulated studies, assent may be waived in accordance with 50.55

Procedure

The Principal Investigator (PI) describes within the IRB application the plans for obtaining assent and permission and, as applicable, provides the informed consent form and the separate assent statement.

The standard screening and review procedures for expedited and convened board review apply.

The IRB reviewer evaluates and approves the plan for obtaining assent and permission and as applicable the related documents. The IRB may require changes to the proposed plan / document prior to granting approval.

Related Policies

2011-006.3 – Additional Protections – Children
2011-007.0 – Definitions Applied to Policies
2011-008.0 – Informed Consent – Forms
2011-008.1 – Informed Consent - Process
2011-008.2 – Informed Consent – Waivers and Alterations
2011-008.5 – Informed Consent – Obtaining and Providing Informed Consent
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by the Convened Board

Basis

21 CFR 50
45 CFR 46

Document Attributes:

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Reviewed and Approved By:

Signed Richard H. Simon

1 May 2017

Richard Simon, MD
Director Human Subjects Protection Office

Date