

Elements of a child's consent form are:

1. Simple familiar English, not slang
2. An explanation of the reason for asking the child to be in the study including:
 - A. The purpose of the study
 - B. Procedures
 - C. Risks or discomforts -- physical or psychological
 - D. Benefits, if any
 - E. Right to refuse or withdraw
 - F. Investigator's willingness to answer questions

When a subject is unable to understand a research project due to age, maturity, psychological state, or brain disease or injury, such a project should not be undertaken unless it provides a reasonable expectation of benefit to the subject and does not interfere with a treatment program. When incompetent adults are sought as subjects for research, the spouse, parent or legal guardian must give informed consent. The consent form should be similar to that for competent adults with appropriate blanks for insertion of the subject's name and for indicating the relationship of the subject's representative to the subject. Make certain that necessary changes are made, recognizing that the signer is not the subject (i.e., a revised right-to-refuse paragraph).

INFORMED CONSENT FOR MINORS AND INCOMPETENT ADULT SUBJECTS

If the subject is a minor between the ages of 13 and 17, both the parent or guardian and the child must give informed consent. The following form must be added **in addition** to all consent forms for subjects in this category:

If a minor is below the age of 13, the informed consent of the parent or guardian must be obtained and the child must be given an explanation of the research. There is a moral obligation on the part of the investigator and the parents (or guardian) to assist the child to understand his/her role in the project. Therefore, under most circumstances, the IRB requires that a simplified consent form be read and explained to children six to twelve years of age. This may entail the use of a consent form especially prepared to facilitate understanding by a minor of such age because even though a parent or guardian has provided consent, the child must also assent to be a subject and sign the form if possible.

Saint Martin's University OMB Control number: _____

IORG number: _____

IRB Approval Date _____

Saint Martin's University
Informed Consent of Minors or Incompetent Adult for Research

Title of the Project:

Investigators:

Advisor:

Department:

Email of the Investigator:

Phone # of the advisor:

ACKNOWLEDGEMENT OF PARENT OR GUARDIAN:

For Adolescents:

I, _____, have also read the preceding and agree to the participation of my child.

Date

Parent/Guardian

Witness