Rush University Medical Center
Policies and Procedures

Procedure Number:	RA-IRB-200
Category Name:	Research
Title:	Elements and Documentation of Informed Consent for Research Subjects
Type:	Policy and Procedure
Revised:	8/2014 (replaces12/2009)

Applies To: Rush Investigators/Study Staff, Rush IRB Members, and IRB Administrative Staff

Policy: **No investigator may involve a human being as a subject in research unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative, except when the Rush IRB has granted an alteration or waiver of consent. The Rush IRB follows applicable federal regulations and RUMC Policy OP-0029 and OP-0074 as they apply to consent in the research setting.**

Definitions

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If a surrogate decision maker is necessary, such an individual must be an adult who (i) has decisional capacity, (ii) is available upon reasonable inquiry; (iii) is willing to make medical treatment decisions on behalf of a patient who lacks decisional capacity and (iv) is identified by the attending physician in accordance with the provisions of the Illinois Health Care Surrogate Act in the following order of priority:

- the patient's (subject's) guardian;
- the patient's (subject's) spouse;
- any adult son or daughter of the patient (subject);
- the parent(s) of the patient (subject), consistent with 21 CFR 50, Subpart D, and 45 CFR 46, Subpart D;
- any adult brother or sister of the patient (subject);
- any adult grandchild of the patient (subject);
- a close friend of the patient (subject);

- the patient's (subject's) guardian of the estate

RUMC Policy #OP-0029 indicates that a legal representative may also include a durable power of attorney identified in writing by an adult patient (subject).

For research subject to Department of Defense (DoD) regulations, when consent is to be obtained from the subjects' legally authorized representative, the IRB must determine that the research is intended to be beneficial to the subject (DoD Instruction 3216.02 (9b)).

Procedure:

Investigators and their study staff are responsible for constructing and submitting a study-specific consent form for review by the IRB and use with potential subjects. The following elements are part of the consent template provided in the Rush Research Portal and are required to appear in the study-specific consent:

1) a statement that the study involves research;
2) an explanation of the purpose(s) of the research;
3) the expected duration of the subject's participation;
4) the approximate number subjects to be enrolled at Rush and, if applicable, the number of subjects to be enrolled at all sites;
5) a description of the procedures to be followed;
6) identification of any procedures which are experimental (i.e. procedures involving the manipulation of the subject physically or psychologically, combination of drugs, new drugs, new devices, etc.);
7) a description of any reasonably foreseeable risks or discomforts to the subject;
8) a description of any benefits to the subject or to others which may reasonably be expected from the research;
9) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
10) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
11) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

12) an explanation of whom to contact for answers to pertinent questions about the research [the Principal Investigator], questions about research subjects' rights [the Research and Clinical Trials Administration Office], and whom to contact in the event of a research-related injury to the subject [Principal Investigator]; and
13) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

If compensation is available for the cost of medical treatment for research-related injury, as outlined above in Item 11, the consent should specify what portion, if any, of the cost of medical treatment will be the responsibility of the subject.

When appropriate, one or more of the following elements of information should also be provided to each subject:

1) A statement that the particular treatment or procedure may involve risks to the subjects (or the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable;
2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regards to the subject's consent;
3) Any additional costs to the subject that may result from participation in the research;
4) When subjects will receive payment or compensation, the amount and schedule of payment and/or compensation;
5) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
6) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject
7) For research that is regulated by the Food and Drug Administration (FDA), a statement that the FDA may inspect the research records.

8) If the study is a study of a drug or biologic subject to FDA regulations (excluding Phase I studies) or a controlled study with health outcomes of devices subject to FDA regulations, a statement that the study description will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law and that the website will not include individually identifiable information.

The informed consent requirements in this policy do not preempt any applicable federal, state, or local laws which require additional information to be disclosed in order to for informed consent to be legally effective.

Informed consent must be documented by the use of a written consent form that embodies the elements of informed consent required above. This form must be approved by the IRB and signed by the subject or their legally authorized representative.

A copy of the consent signed by the subject or their legally authorized representative and person obtaining consent will be given to the subject and/or their legally authorized representative. The only exceptions to the informed consent documentation requirement are: (a) individual studies which have been certified as "Exempt" from IRB review by the RCTA; and (b) individual studies where the Rush IRB has waived the requirement to obtain all or elements of informed consent (see IRB Policy and Procedure RA-IRB-201 "Alteration or Waiver of Informed Consent).

The consent form may be read to the subject or representative, but in any event, the investigator shall give either the subject or representative adequate opportunity to read it before it is signed. Unless otherwise required by federal regulations (see RA-IRB-202) or instructed by the IRB, the signature of the subject or their legally authorized representative must be witnessed by an individual who is present at the time the patient signs the consent form. The witness may be the individual obtaining consent or the subject's family member or friend. The function of the witness is to attest to the following facts to the best of their knowledge:

a. The person signing the consent form is the subject or the subject's legally authorized representative (when applicable); and

b. The person signing the form has done so voluntarily.

Obtaining consent and assent in research involving children (minors) must be conducted in accordance with IRB Policy and Procedure RA-IRB-206 “Research Involving Children (Minors)”.

Obtaining informed consent is a process. Investigators and their study staff must ensure that subjects and/or their legally authorized representatives are clearly informed that they may refuse to participate or that they may withdraw their consent at any time without penalty or loss of benefits to which they would otherwise be entitled.

Informed consent is more than just a signature on a form; it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding. Rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and/or their designee and the subject.

The consent process must be documented in the research record that a copy of the signed consent form was given to the subject, the subject met all inclusion and no exclusion criteria at the time of consenting, all their questions were addressed (if any) and adequate time was given for informed consent to take place. When subjects are enrolled in an in-patient setting, a copy of the consent form should be filed in the medical record.

Reference	45 CFR 46.116, 21 CFR 50.25, Department of Defense Instruction 3216.06 (9b), RUMC Policy OP-0029, RUMC Policy OP-0074
Related Documents	Consent Template

Last Reviewed: 8/7/2014