**GUIDANCE 38**

**GUIDELINES FOR CONSENT PROCEDURES AND CONSENTING PROCESS**

**ARTICLE 5 OF RU GUIDANCE ON CONSENT**

**Consent Procedures and Consent Forms (45 CFR 46.117 and 21CFR Part 50)**

Informed consent is one of the primary ethical requirements of research with human subjects, reflecting the basic principles of Belmont Report, Respect for Persons, Beneficence, and Justice. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

For further guidance on consent requirements and process go to the following links: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm>. and <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html>.

Informed consent should assure that prospective human subjects understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. This assurance protects all parties, including the investigator and the Institution, who may otherwise face legal hazards.

The "Surrogate consent" of someone other than the subject is not the same as the subject's own consent. An acceptable substitute, when a subject is unable to give informed consent, is primarily governed by law of the state where the consent is signed or study is being conducted. Surrogate consent is permitted with certain limitation in the State of New Jersey when subjects are unable to give their own consent. The state law and the Institution’s policy require surrogate (proxy) consent or permission from a legally authorized representative, or some individual who has been previously designated for healthcare proxy. Broad consent may be obtained in lieu of informal consent with respect to storage, maintenance, and secondary research uses identifiable private information and identifiable biospecimens for secondary research purposes.

**Guidelines for Parental permission, Assenting Minors on a research project and Assent Waiver for Children are provided in Article 6, Subpart D, Section 6.26.**

**Informed consent FAQs form the Office for Human Research Protections (HHS.gov) is provided in the following link:** [**https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html)**.**

**2. Tips on Informed Consent**

The process of obtaining informed consent must comply with the requirements of OHRP and FDA (**Appendix 2 and 3 of RU guidance book**). The documentation of informed consent must comply with Federal regulations and university policies. These Federal regulations can be found at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html>. The following suggestions may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by IRBs.

A. Informed consent is not just a form - Information must be presented in detail to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand.

B. Informed consent must begin with a concise and focused presentation of the key information that is most likely to affect a prospective subject or Legally Authorized Representative in understanding the reasons why one might or might not want to participate in the research. This must be presented in a form that facilitates comprehension and understandable to the people being asked to participate.

C. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in such a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one may or may not want to participate.

D. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject’s legal rights or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

E. Describe the overall experience that will be encountered - Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted.

F. Describe the benefits that subjects may reasonably expect to encounter - There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.

G. Describe any alternatives to participating in the research project - For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.

H. The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence - For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.

I. If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see Appendix 3) an explanation must be given of whatever voluntary compensation and treatment will be provided - Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation.

J. The regulations prohibit waiving or appearing to waive any legal rights of subjects - Consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

K. The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, their rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation - A single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

L. The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations - It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function. Don't forget to ensure provision for appropriate additional requirements which concern consent. The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in the consent document.

M. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

* 1. A statement that the particular treatment or procedure may involve risks to the subject (or to 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 regard to the subject's consent;
  3. Any additional costs to the subject that may result from participation in the research;
  4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
  5. 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; and
  6. The approximate number of subjects involved in the study.

**3. Consent Process**

Informed consent is an ongoing process, not something the investigator hands out to the prospective subject at the time of consenting. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. This assurance protects all parties, both the subject, whose autonomy is respected, and the investigator. A primary ethical responsibility of the Principal Investigator is to ensure that potential participants have been provided with all the information they might reasonably need to know. Any research protocol utilizing human participants requires the informed consent of those participants. Potential participants have the right to know what they are being asked to do prior to voluntary participation, no matter what the nature of the protocol and no matter how innocuous it may seem. The procedure of advising potential participants and obtaining voluntary agreement is known as the informed consent process. The process includes:

1. The consent document is to be used as a guide for the verbal explanation of the study;
2. The consent document should be the basis for a meaningful exchange between the researcher and the participant;
3. The participant's signature provides documentation of agreement to participate in a study, but is only one part of the consent process.

Regulations require that the PI must document **(45 CFR 46.117)** the informed consent of each subject on a consent form approved and stamped by the IRB. Each IRB approved document must be signed and dated by the investigator or persons designated in the consent form as authorized to obtain consent, the person obtaining the consent, and the subject or his/her legally authorized representative. The IRB will approve procedures for verbal, electronic or implied consent only under exceptional circumstances.

**4. Standard Operating Procedures for Informed Consent**

Respect for Persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. The IRB may approve the following recruitment procedures for enrolling research participants in your project**.**

A. PI will insure that informed consent is obtained from each subject prior to the start of his or her participation in a clinical or behavioral research study.

B. Only an IRB approved and stamped consent form is to be used for consenting subjects. A copy of the consent form should be provided to the participant.

C. Each consent form will contain the following:

* + - * 1. Institution’s Name;
        2. Name of the Study;
        3. Investigator's Name;
        4. Subject's Name;
        5. Location where study will be done;
        6. Entity where research will be conducted;
        7. Sequentially numbered pages;
        8. Authorization for collecting Protected Health Information;
        9. Space for subject’s initials on each page;
        10. Version number or version date of the current consent form noted in the footer;
        11. IRB stamp on each page indicating the approval and expiration date;
        12. A consent signature page for subject, investigator or other individuals. authorized by the IRB to obtain consent, and witness signature to sign;

D. The process should eliminate possibility of coercion of undue influence and eliminate use of exculpatory language;

E. The informed language should be understandable and written at or about 8th grade level using layman’s terms and in a language that is understandable to the subject;

F. The PI, other designated investigators, study coordinators, or other persons authorized to obtain consent will review the consent form with potential study subjects;

G. Potential subjects will be informed whether the study involves the use of experimental devices or drugs, what the long-term health-related implications are, and how subjects’ quality of life may be affected;

H. The potential subject will receive a copy of the informed consent to read. The coordinator or PI will review each aspect of the study and answer all questions;

I. If the subject wishes to speak with the principal investigator before signing the consent, a meeting will be scheduled to have all questions answered prior to the subject's signing the document;

J. If the subject chooses to take a blank consent home to reread or discuss with family members, personal physician, or an attorney, a copy of the consent will be provided;

K. Consent forms must be signed and dated by the participants or their legal representatives or surrogate prior to beginning any study-related procedures;

L. If a surrogate is providing consent for the subject, the surrogate must receive some education about their role, the cognitive, and health status of the research participant, as well as about the study in which the participant may be involved before their consent may be requested. The surrogate must be informed of the risks, benefits, and alternatives to research before they give consent for an individual to participate. Such training must be documented;

M. Consent forms must be signed and dated by a witness (only when required by the IRB) and/or the investigator or other persons authorized to obtain consent as required by the IRB and the sponsor;

N. Investigators may pre-screen research subjects as approved by the IRB by personal interview, telephone screen, or chart reviews to determine general eligibility for a study prior to the informed consent being signed;

O. Prior to signing the consent form, the subject or surrogate will be asked to reply, in his or her own words, and without immediate reference to the consent form, to the following questions.

* + - * 1. What is the purpose of this study?
        2. What will be done?
        3. What risks and discomforts may occur from participating in this study?
        4. What benefits may the subjects gain from participating in this study?
        5. Ask the subjects to repeat in their own words about the goal of the research study. What will happen to them if they agree to be in the research study?
        6. What do they expect to gain by participating in the study?
        7. Tell them what will happen if they do not wish to participate in the study.
        8. Tell them what will happen if they change their mind not to participate once the study has started.
        9. Do the participants have any questions to ask back to you?

P. Inform the prospective subject that they can take the consent form home have it read by others before they give consent;

Q. Advise them to keep a copy of the consent form and the information to contact the researcher in a safe place in case they have to contact the researcher;

R. A subject may participate in a study only if his/her answers demonstrate an informed understanding;

S. If a protocol involves major risks; the IRB may require that subjects or the surrogate must be briefed twice with at least two (2) days between briefings. If it is anticipated that the second briefing may have to be waived in some circumstances, the PI should include such information at the time of initial review;

T. All research subjects will be asked to initial every page of the informed consent to document that all pages were presented during the informed consent discussion;

U. For clinical trials, the investigator will maintain an informed consent documentation sheet in the study binder indicating the name of the study, and the time and date of informed consent signed and when the IRB approval will expire and

V. The investigator MUST maintain a copy of the signed consent form with the study specific regulatory binder, or as an appendix, in a secure location readily accessible to the investigator and that must be included in the initial protocol or at the time of modification.