

SUBJECT: Informed Consent	Effective Date: March 5, 2018	Policy Number: 10.3.10. Version 3
	Supersedes: November 14, 2014 October 21, 2011	Page 1 of 6
	Responsible Authorities: Vice President, Research Institutional Review Board Assistant Vice President Research Integrity	

I. Background

Informed consent is one of the fundamental principles of ethical conduct in human subjects research. It is mandated by Federal regulations 45 CFR 46.116 and 46.117, as well as 21 CFR Subpart B. In addition, Florida Statutes will apply when they provide consent requirements above and beyond federal regulations.

II. Purpose

To provide guidance to investigators and other authorized research personnel in obtaining and documenting informed consent when enrolling human subjects in research.

III. General Statement

All human subjects research conducted under the auspices of Florida Atlantic University shall comply with the provisions set forth in 45 CFR 46.116, 45 CFR 46.117, and 21 CFR Subpart B (for applicable studies) regarding informed consent.

IV. Policy

- **No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative.** In seeking such consent, the investigator shall provide the prospective subject or the subject's representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- **Unless a waiver is granted in accordance with 45 CFR 46.117(c), informed consent shall be documented by the use of a written consent form approved by the IRB**

and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form, and the original should be retained by the PI.

- **The informed consent document(s) that the FAU PI submits to the IRB should be tailored to the educational level and readability needs of participants**, and must include the eight basic informed consent elements as outlined in 45 CFR 46.116(a) (b), 21 CFR 50.25, and the FAU informed consent templates.

The basic informed consent elements are:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) 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;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) 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.
- (9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

As appropriate, additional elements of informed consent should also be included:

- (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.
- (7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

FDA regulated studies should contain the required consent elements outlined in 21 CFR 50.25.

- **The informed consent form may be read to the subject or the subject's legally authorized representative**, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.
- **A shorter written consent document that contains the elements of informed consent required by 45 CFR §46.116 may be presented verbally to the subject or the subject's legally authorized representative.** *This generally applies to subjects who have low literacy levels.* When this method is used, there shall be a witness to the verbal presentation. Also, the IRB shall approve a written summary (e.g. script) of what is to be said to the subject or the representative. The short form is signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.[45 CFR 46.117 (b)(2)]

- **No informed consent, whether verbal or written, may include any “exculpatory language”** through which the subject or the 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. [45 CFR 46.116]
- **The IRB may require special monitoring of the consent process by an impartial observer (consent monitor) to reduce the possibility of coercion** and undue influence. Observation of the consent process may be performed by a member(s) of the IRB or IRB support staff, FAU auditor, a consent monitor appointed by the IRB, or by a third party hired by the Principal Investigator or Sponsor. ***Examples of when special monitoring may be required are:* a) during the enrollment of vulnerable populations; b) enrollment of individuals in situations of duress, or c) during the explanation of very complex studies with multiple procedures occurring at various times.
- Consent forms must be translated into an appropriate language if the research subjects do not speak or comprehend English.
- The FAU IRB shall follow its policy on Children in Research with regard to informed consent provisions specific to children in research. Provisions for child assent and parental permission are specifically outlined in this policy. Similarly, the FAU IRB shall be guided by its policy, Research Subjects with Cognitive Impairment, when assessing informed consent provisions specific to cognitively impaired populations. Both of these related policies are consistent with the main policy outlined here, and stem from the same core regulations.

V. Definitions

Informed Consent: An individual's voluntary agreement to participate in research based upon adequate knowledge and understanding of relevant information. (“Relevant information” refers to the basic informed consent elements as outlined above in section IV and the FAU informed consent templates.)

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Obtaining and documenting informed consent in accordance with this policy from each prospective participant or their legally authorized representative prior to the conduct of any activities that constitute the research encounter, unless the requirement of informed consent is waived or altered by the IRB.
- Ensuring the information provided to the participant or the participant's legally authorized representative accurately conveys study procedures, is in a language understandable to the participant or their representative, and provides sufficient opportunity for the participant or their representative to consider without coercion whether or not to participate.
- Ensuring that the informed consent process is executed by: a) Someone knowledgeable about the research; b) Someone able to answer a prospective participant's questions about the research; and c) someone that has been approved to act in this capacity by the IRB.
- Ensuring that the IRB approved informed consent document: a) contains a valid IRB approval

stamp; b) the dates of approval on the document are valid; c) The participant is provided a complete copy of the consent document; and d) A signed copy of the consent document is maintained in the Principal Investigator's research records. (The most current version, inclusive of any related amendments.)

The IRB will be responsible for:

- Ensuring that informed consent provisions provided as part of the IRB submission are adequate, appropriate and justified in relation to the population and the applicable regulations.
- Ensuring that the required elements of informed consent are included in the consent documents provided and reviewed.
- Observing or having a third party observe the consent process and the research, when warranted.
- Verifying that the informed consent document used to enroll participants is the IRB-approved version.

The Research Integrity office will be responsible for:

- Ensuring that informed consent documents are included as part of the IRB submission package.
- Verifying that the required elements of informed consent are included in the consent documents submitted.
- Upon final IRB approval, ensuring that the stamped consent form(s) are provided to the PI.

VII. Procedures

- The PI should submit the IRB application package electronically via IRBNet. Note that no enrollment or consenting of subjects can occur until after IRB approval has been granted for the protocol and corresponding consents.
- As part of the IRB application package, the PI must include the informed consent documents most appropriate for the study (e.g., an adult consent form for adult participants, a child assent for child participants), and ensure the informed consent document is in a language and reading level understandable to the participant or their representative. Further, the PI should take into account the medium through which informed consent will be carried out (for example, in online environments) and tailor the consent process appropriately. **Note: If the PI is not including a consent document that requires a signature, see policy on Waiver of Informed Consent, for alternatives to the traditional informed consent form.
- The PI should describe in the protocol how the informed consent process will be carried out. Ensure the informed consent process provides sufficient opportunity for the participant or the participant's legally authorized representative to consider whether or not to participate.
- The PI must ensure that the informed consent process is conducted by: a) someone

knowledgeable about the research; b) someone able to answer a prospective participant's questions about the research; and c) someone that has been approved to act in this capacity by the IRB.

- After obtaining IRB approval and as each participant is enrolled, the PI should ensure:
a) only the IRB approved informed consent document with a valid IRB approval stamp is used; b) the consent document has valid IRB approval dates; c) the participant is provided a complete copy of the consent document; and d) the consent documents are securely maintained in the Principal Investigator's research records.

VIII. Policy Renewal Date

TBD

IX. References

45 CFR 46.102(c)
45 CFR 46.116
45 CFR 46.117
21 CFR Subpart B

POLICY APPROVAL

Initiating Authority

Signature:

Date:

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)