FLORIDA ATLANTIC UNIVERSITY

Division of Research

SUBJECT: Waiver of Informed Consent	**Effective Date:** March 30, 2018	**Policy Number:** 10.3.11 Version 3
	Supersedes: November 14, 2014 October 21, 2011	**Page 1 of 4**
	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. However, federal regulations allow for the waiver of documented informed consent, or complete waiver of informed consent in human subjects research under specific circumstances. [45 CFR 46.116 (c)(d), 45 CFR 46.117, 21 CFR 50.23 and 50.24].

"Documented informed consent" refers to the traditional informed consent form that is signed by the research participant. Complete "waiver of informed consent" refers to non-use of either a verbal or written informed consent process.

II. Purpose

To provide guidance to investigators and other authorized research personnel on when a) a waiver *of documented informed consent* or b) a complete *waiver of informed consent* is permissible in human subjects research, and to outline procedures for requesting IRB approval of such a waiver.

III. General Statement

Informed consent is a process. Therefore, documentation of the consent process via a signed consent form is not always required. Instead, verbal consent might be more appropriate for certain populations (including non-literate or politically vulnerable populations) or certain types of anonymous, low-risk research. Verbal consent means that the potential research subject is read a verbal version (script) of the consent form.

Alternatively, a consent paragraph that precedes an anonymous survey, or a consent letter are sometimes acceptable, both of which do not require a participant's signature.

Occasionally, there are reasons to waive both written and verbal consent under certain circumstances based on the nature of the research. While the researcher may propose alternative informed consent mechanisms, only the IRB can make the final determination to waive some or all informed consent requirements

IV. Policy

The FAU IRB may approve a consent process which does not include, or which alters, some or all of the elements of informed consent referenced in 45 CFR 46.116(a), or it may waive the requirements to obtain informed consent if the IRB finds and documents that all four of the following are met:

- The research involves no more than minimal risk to the subjects;

- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; (Inconvenience or expense are not acceptable factors. Scientific validity could be an acceptable factor); and

- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

In addition, the FAU IRB may approve a consent process which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- It is a research or demonstration project to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

- The research could not practicably be carried out without the waiver or alteration of consent elements.

The FAU IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- The principal risks are those associated with a breach of confidentiality regarding the subject's participation in the research, and the consent document is the only record linking the subject to the research; and

- Study participation presents minimal risk of harm to the subject, and the activity normally does not require consent except for the fact that this is a research study.
- In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

The FAU IRB shall follow its Children in Research policy when applying waiver of informed consent provisions specific to children in research. Provisions for waiver of assent or parental permission are specifically outlined in this policy, and are consistent with the policy outlined here.

Researchers may also request a waiver of consent in emergency care research. This typically occurs in health care settings and applies to human subjects who are in a life threatening condition where an investigational therapy may be beneficial, but there is not enough time to obtain legal informed consent. The federal regulations (21 CFR 50.23 and 50.24) describe the situations where this can occur. This provision has limited applicability at Florida Atlantic University.

V. Definitions

Informed Consent: An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research.

VI. Accountability

The Principal Investigator (PI), if seeking a consent waiver, will be responsible for:

- Submitting a request for waiver of documented informed consent, or complete waiver of informed consent, as part of the IRB application package when the standard informed consent document with signature line is determined to be inappropriate for the research study, based on the study methodology.

- Submitting an alternate method(s) of informed consent as part of the IRB application package in lieu of the standard informed consent document with signature line.

- Maintaining a method of documenting those who were approached about the study and offered verbal consent, in lieu of the standard informed consent procedures requiring signature.

The IRB will be responsible for:

- Ensuring that the request for waiver of documented informed consent, or complete waiver of informed consent, is adequately justified with respect to the applicable regulations.

The Research Integrity office will be responsible for:

- Ensuring that the request for waiver of documented informed consent, or complete waiver of informed consent, is included with the IRB application package when no standard informed consent document with signature line is submitted by the PI.

- Ensuring that alternate methods of informed consent are submitted in lieu of the standard informed consent document with a signature line.

- Ensuring documentation of any IRB approved waiver of informed consent is maintained on file.

- Providing the IRB with the criteria for informed consent waivers to assist in their decision making.

VII. Procedures

To request a waiver of documented informed consent (in other words, to not use a consent form that requires a signature), the PI should:

- Include a request for waiver of documented informed consent as part of the IRB protocol. It is important that the PI discuss and justify the rationale for this requirement to be waived by the IRB. The request must address how the proposed research meets the following criteria: a) The principal risks are those associated with a breach of confidentiality regarding the subject's participation in the research, and the consent document is the only record linking the subject to the research; and b) Study participation presents minimal risk of harm to the subject, and the activity normally does not require consent except for the fact that this is a research study.

- As part of the IRB application, submit a proposed script of the verbal consent process, or alternative consent document (e.g., cover letter, consent paragraph, etc.)

Recommendations:

- When verbally consenting subjects, it is *recommended* that you hand out a separate business card or information sheet to subjects with relevant contact information. In addition, it is *recommended* that investigators keep a log of those who were approached about the study and offered verbal consent. A simple chart, numbered sequentially without identifiers, is sufficient. It is important to keep some record to indicate that you are not enrolling more subjects than the number approved in the IRB application.

To request a waiver of both written and verbal informed consent, the PI should:

- Include a request for waiver of both written and verbal informed consent as part of the IRB protocol. It is important that the PI discuss and justify the rationale for this requirement to be waived by the IRB. The request must address how the proposed research meets the following criteria:
    a) The proposed research presents no more than minimal risk of harm to subjects.
    b) The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
    c) The research could not practicably be carried out without the waiver or alteration. (It is not sufficient to say you don't have enough money, time, or resources to carry out this function) and
    d) Whenever appropriate, the subjects will be provided with additional pertinent information (e.g., a debriefing) after participation. If a debriefing statement is to be used, it should be included in the IRB submission.

VIII. Policy Renewal Date
As needed

IX. References
45 CFR 46.116, 46.117
21 CFR 50.20, 50.23, 50.24, 50.27

POLICY APPROVAL

Initiating Authority

Signature: Date: 3/23/2018

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

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