



## Division of Research Policy

<b>SUBJECT:</b>  Use of Legally Authorized Representatives (LAR) for Research Subjects with Cognitive Impairment		<b>Policy Number:</b> 10.3.2
	<b>Effective Date:</b> October 9, 2015	<b>Renewal Date:</b> August 1, 2018
	<b>Supersedes:</b> May 30, 2014 October 21, 2011	<b>Page 1 of 5</b>
	<b>Responsible Authorities:</b> Vice President, Research Institutional Review Board Director, Research Integrity	

### I. Background

State and federal human subjects regulations require that consent for research be obtained from the participant's legally authorized representative (LAR) if the subject lacks the capacity to consent (45 CFR 46.116; 21 CFR 50.20.)

### II. Purpose

The purpose of this policy is to establish guidelines for identifying who can act as a legally authorized representative when enrolling an individual with a cognitive impairment as a research participant in a study reviewed by the FAU Institutional Review Board (IRB). This policy also documents the responsibilities of the Principal Investigator (PI) and the IRB in ensuring that persons who lack the ability to consent due to cognitive impairment are consented properly prior to enrolling in a human subjects protocol and throughout their participation in that protocol.

### III. General Statement

The Board recognizes the importance and value of including persons with cognitive impairment and/or mental/psychiatric illness in research, particularly when such research may help society better understand their condition, treat it, and improve their quality of life.

However, the benefits of such research do not outweigh the fact that potential subjects may have a cognitive impairment that affects their ability to understand the responsibilities and implications of the research to which they are consenting. Therefore, individuals recruited and enrolled in a research protocol reviewed by the FAU IRB must a) participate in a consenting process that is both ethical and respects the legal rights of the subject and their family, and b) if warranted, be represented by an individual who has the legal authority to act on behalf of that person and who meets the definition of legally authorized representative as set forth in DHHS and FDA regulations [45 CFR 46.102(c); 21 CFR 50.3(l)].

The IRB expects informed consent to be a process, where the PI will seek informed consent through a dialogue with the potential subject in addition to obtaining proper documentation of the subject and LAR's signatures on the informed consent form. Researchers may use assessment tools (such as the Mini-Mental State Examination (MMSE)) and similar instruments to quickly assess cognitive capability/competence to determine whether the subject has the cognitive capacity to provide consent. In using these instruments, it is important that researchers adopt the guidance about acceptable cut-off scores from recognized and scientifically specialized bodies (e.g., American Psychiatric Association, American Psychological Association, etc.) and/or current scientific literature for subject enrollment. In these cases, the researcher acts in the best interest of the human participant and for the prudent benefit of the study.

#### IV. Policy

If a PI plans to recruit and enroll individuals who may have a cognitive impairment that affects their ability to consent, they should assess the subject's capability of consenting to determine if an LAR is needed. Assessment is usually based on an objective scale or instrument (such as the MMSE) in conjunction with observation by a qualified, licensed health professional (e.g., physician, nurse, psychologist, LCSW, etc.)

If the PI elects to use the MMSE to assess the subject's capacity to provide consent, and the subject scores  $\leq 23$  (less than or equal to 23) on this scale, the subject is presumed to be incapable of consenting for him-/herself unless there is other documentation demonstrating competency and the signature of a Legally Authorized Representative is required. The conclusion of incompetency must be documented with the subject's records and is applicable only to the particular study. Subject assent must be obtained and recorded per Section VII of this document. For those persons scoring  $>23$  (24 and above), the subject is presumed to be competent to consent for him-/herself unless there are indications otherwise.

The PI may elect to use other assessment tools or instruments to determine the subject's competency. In using any instruments, it is important that researchers adopt the guidance about acceptable cut-off scores from recognized and scientifically specialized bodies (e.g., American Psychiatric Association, American Psychological Association, etc.) and/or current scientific literature for subject enrollment. This guidance must be explained and justified as part of the protocol procedures.

The PI must continue to assess the subject's competence (as outlined in Procedures below) to ensure there has been no regression in their cognitive status and that the participant continues to understand the responsibilities, risks, and benefits of study participation.

#### V. Definitions

**Legally authorized representative:**

Federal (DHHS and FDA) regulations define a legally authorized representative as an individual, 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 [45 CFR 46.102(c); 21 CFR 50.3(l)]

In the State of Florida (765.401, Fla. Stat.), individuals who serve as proxy or surrogate are recognized as the subject's legally authorized representative and have the ability to consent to participation in human research, in the following order:

- *Health Care Surrogate.* Individual named by a person while that person is still competent to act. (765.101 (16), Fla. Stat.)
- *Guardian.* Individual appointed by the court and specifically authorized by the court to enroll the individual in the human research study. (In the State of Florida, a guardian must have court appointed authority for a specific research activity before he/she can give consent for a child's participation in research.)
- *In the absence of an Advance Directive, an Authorized Individual.* Individual who is authorized under applicable state or local law to consent on behalf of the subject to general medical care including when that care involves research. [45 CFR 46.402(e); 21 CFR 50.3(s)].
- *The person's spouse.*
- *An adult child of the person,* or if the person has more than one adult child, a majority of the adult children who are reasonably available for consultation.
- *A parent of the person.*
- *The adult sibling of the person,* or if the person has more than one sibling, a majority of the adult siblings who are reasonably available for consultation.
- *An adult relative of the person* who has exhibited special care and concern for the person and who has maintained regular contact with the person and who is familiar with the person's activities, health and religious and moral beliefs.
- *A close [adult] friend* of the person who has also shown special care and concern for the person.
- *A clinical social worker* licensed pursuant to Chapter 491 of Florida Statutes, or who is a graduate of a court-approved guardianship program. Such a proxy must be selected by the IRB and must not be employed by, or under the supervision of, the PI

For research conducted in other States or territories, the legal definition of legally authorized representative will be determined by reference to the law of that state or territory.

**VI. Accountability****The Principal Investigator (PI) will be responsible for:**

- Ensuring legally authorized informed consent is obtained for each individual prior to being enrolled in a human subjects research protocol.

- Ensuring legally authorized informed consent is obtained from the proxy or surrogate, as defined by DHHS and FDA, who is highest on the hierarchy available (see Section V, Proxy or surrogate) and documenting justification for why someone higher on the hierarchy was not sought for legally authorized informed consent.
- Obtaining assent from the individual actually participating in the research if an LAR is used to obtain informed consent.
- Documenting initial as well as ongoing consent to participate.

**The Institutional Review Board (IRB) will be responsible for:**

- Ensuring legally authorized representation is provided for every research participant with cognitive impairment that affects his/her ability to consent for his- or herself.
- Ensuring that enrollment of cognitively impaired populations meets all ethical standards and federal requirements.
- Ensuring that additional protections have been incorporated into the study to provide added protection for individuals with cognitive impairment.

VII. Procedures

- Unless otherwise waived by the IRB, the PI must obtain an informed consent form signed AND dated by:
  - The subject, and/or
  - The subject's legally authorized representative (LAR). (If an LAR is required, he/she should sign as an indication of "consent" and, if possible, the subject should sign indicating "assent"). If the subject cannot sign, the investigator will document waiver of written assent in writing.
  - The person conducting the consent interview.
- The PI must maintain an original signed consent document in the research files. IN ADDITION, the PI is also required to:
  - Provide one copy given to the subject and, if applicable, his/her LAR.
  - Provide one copy for the subject's official medical record, *if applicable*.
- For **initial** informed consent, the PI must place a detailed note in the file that documents how the subject understood what was explained verbally and/or in the consent document. A statement that "the subject understood the information presented" is not adequate as it does not explain how this was determined. In general, the more detailed the note, the better. Examples on how this is determined may include but are not limited to:
  - A written assessment of subject's recollection of key study points.
  - Verbal recollection of most key study points.
  - Documentation of subject's mental status as it pertains to decision-making at the time of consent. (required)

- For **ongoing** consent, at each visit (if applicable), the PI must place a detailed note in the file that details the subject's willingness to continue in the study as well as the subject's understanding of the study. This note should include sufficient information to determine that the subject is capable of making and has provided informed consent. Similar to above, a note simply stating "subject wishes to continue in study" is not sufficient. This statement does not adequately demonstrate how it was determined that the participant remains in a state of continued informed consent. Examples on how this might be determined may include but is not limited to:

- A written assessment of subject's recollection of key study points.
- Verbal recollection of most key study points.
- Verbal acknowledgement of understanding any amendments to the protocol or a newly developed risk(s).
- Documentation of subject's mental status as it pertains to decision-making at the time of consent. (required)

After ongoing assessment, if the subject is deemed incapable of continuing to provide informed consent, the subject's LAR should be sought for re-consenting. Until the LAR's consent can be obtained, the subject should not be involved further in study procedures. If an LAR cannot be obtained, the subject should be withdrawn from the study. The PI is advised to consult with the Research Integrity office under these circumstances.

VIII. Policy Renewal Date

08/01/2018

IX. References:

45 CFR 46

21 CFR 50

Florida Statutes 765.204 and 765.401

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POLICY APPROVAL

*Initiating Authority*

Signature:

Date:

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

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