UNIVERSITY OF SOUTH ALABAMA

IRB SOP 904
Research Involving Decisionally Impaired Participants

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe additional protections for decisionally impaired participants.

Scope

This SOP applies to Investigators whose research involves decisionally impaired participants.

Policy

It is the policy of the IRB that research involving decisionally impaired participants who cannot provide voluntary consent or assent include additional protections in accordance with DHHS 45 CFR §46.111(b).

Decisionally impaired persons are those who have a diminished capacity for autonomous decision making due to a psychiatric, organic, developmental or other disorder that affects cognitive or emotional functions. Other individuals who may be considered decisionally impaired, with limited decision-making ability, or individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps. There are no regulations specific to research involving cognitively impaired persons.

The National Bioethics Advisory Commission (NBAC) has issued 21 recommendations for IRBs, the research community, and Federal regulators to consider regarding the decision-making capacity of particularly vulnerable participants. The complete report, "Research Involving Persons with Mental Disorders That May Affect Decision Making Capacity" (December 1998), can be found on-line at https://govinfo.library.unt.edu/nbac/capacity/TOC.htm.

Procedures

1.0 Review Requirements

Although not specifically addressed in the regulations as a vulnerable population, the University of South Alabama IRB requires additional safeguards for research involving persons with decisional impairment. The IRB will approve the research only if it finds that:

1. the research bears a direct relationship to the decisionally impaired subject's condition or circumstance;
2. the research meets one of the following criteria:
    - presenting no greater than minimal risk to the involved subjects;
    - presents an increase over minimal risk to involved subjects, but which offers the potential for direct individual benefit to the subject;
    - presents a minor increase over minimal risk to involved subjects and which does not have the potential for direct individual benefit; provided that the knowledge sought has direct relevance for understanding or eventually alleviating the subjects' disorder or condition.

In evaluating a protocol involving the enrollment of persons with decisional impairment, the IRB may consider requiring additional safeguards, as appropriate, for a given protocol. Such safeguards may include any of the following:

- use of an independent party (independent of the study investigator with appropriate expertise) to assess the capacity of the potential subject;
- use of standardized assessment of cognition and/or decisional capacity;
- use of informational or educational techniques;
- use of an independent person to monitor the consent process;
- use of waiting periods to allow for additional time to consider information about the research study;
- use of proxy consent;
- use of assent in addition to proxy consent in order to respect the autonomy of individuals with decisional impairment;
- use of a witness. The IRB will determine the following when choosing this option:
    - whether the witness needs to be unbiased (which means the individual is not part of the study team nor a family member of the potential participant)
    - whether the witness will observe the entire consent process or just the signature

2.0 Consent

In general, all adults, regardless of diagnosis or condition, should be presumed competent to consent to participation in research unless there is evidence of serious disability that would impair reasoning or judgment. In making the determination about whether it is appropriate for investigator's to utilize proxy consent, the IRB will take into consideration the following:

- the rationale for the need to obtain proxy consent;
- the criteria that will be used in determining whether a potential subject has decisional impairment sufficient to require the use of proxy consent, including any use of standardized assessment tools;
- whether any additional methods are proposed to enhance subjects' ability to achieve decisional capacity with regard to the proposed study (e.g., reading of the consent form may not be sufficient and use of other tools such as videos, educational materials, post-test, etc. might be considered to assist potential subjects in understanding what is involved with the research);
- who will be approached, and in what order, to provide proxy consent.

The following are specific procedures that must be followed if proxy consent is utilized:

- Persons with decision impairment may also have been adjudicated legally incapacitated by a court decision. If such persons are considered for enrollment in a research protocol, the only party who may provide proxy consent is the court-appointed guardian. The guardian may only provide proxy consent if the court order, appointing them guardian, *specifically states that they have the authority to enroll the incapacitated person into a research protocol*. For this category of subjects, a copy of the court order appointing the guardian and granting the guardian authority to enroll the person into a research study should be attached to the informed consent document.
- Persons may also, through a health care proxy appointed by a power of attorney, designate a person to make decisions for them in the event that they are subsequently incapacitated. This person may give proxy consent for enrollment of a subject in research.
- If a potential subject has neither a guardian, nor a health care proxy designated, the investigator may obtain the informed consent of the subject's legally authorized representative. Where neither a court-appointed guardian, nor a health care proxy exists, investigators may seek informed consent from the following individuals, in the order listed below:
    - spouse, unless an action for divorce is pending, and the adult children of the principal are not the children of the spouse;
    - adult child
    - a parent (natural or adoptive);
    - adult brother or sister;
    - grandparent
    - an adult who has knowledge of the principal's preferences and values, including, but not limited to, religious and moral beliefs, to assess how the principal would make health care decisions

When a person is giving proxy consent, the proxy should be informed that, where possible, s/he should base the decision on substituted judgment, reflecting the views that the subject expressed while decisionally capable. The proxy should be fully informed on the risks, benefits

and alternatives to the research. If the values of the subject are not known with respect to a proposed research study, the proxy should act in the best interest of the subject.

If a person with decisional impairment is capable of exercising some judgment concerning the nature of the research and participation in it, the investigator should obtain the subject's assent in addition to the consent of his/her legally authorized representative.

The verbal objection of an adult with decisional impairment to participation in the research should be binding. If the subject, at any time, objects to continuing in the research study, such objection should be respected.

Where the condition causing the subject's decisional impairment is of an intermittent or temporary nature, the informed consent process should include a mechanism for obtaining the subject's subsequent direct informed consent to participate in the research. If a subject regains decision making capacity and declines to continue in the research, the decision must be respected.

2.1 Documentation of Consent and Assent: Research Record

In studies in which some or all participants may have decisional impairment, it is recommended that at the time of obtaining consent the following be documented in a note to file for the subject's research record:

- whether the subject demonstrated the ability to understand the nature of the research procedures, the potential risks and benefits, the voluntary nature of the participation and to make a personal judgment about participation;
- use of any supplemental methods to enhance or evaluate decisional capacity;
- a summary of the matters discussed with the subject's legally authorized representative.

3.0 Determination of Decision-Making Capacity

The decision-making capacity of a potential research subject should be evaluated when there are reasons to believe that the subject may not be capable of making voluntary and informed decisions about research participation. The investigator and research staff must have adequate procedures in place for assessing and ensuring subjects' decisional capacity, understanding, and consent capacity or to give assent. The IRB will evaluate whether the proposed plan to assess capacity to consent is adequate. For research protocols that involve subjects with mental disorders that may affect decision-making capacity, the IRB may determine that capacity assessments are necessary, unless the investigator can justify why such assessments would be unnecessary for a particular group.

For research protocols involving subjects who have fluctuating or limited decision making capacity the IRB may ensure that investigators establish and maintain ongoing communication with involved caregivers. Periodic re-consent should be considered in some cases. A re-

consenting process with surrogate consent may be necessary. Third party consent monitors may be used during the recruitment and consenting process, or waiting periods may be required to allow more time for the subject to consider the information that has been presented.

It is often possible for investigators and others to enable persons with some decisional impairment to make voluntary and informed decisions to consent or refuse participation in research. Potential measures include repetitive teaching, group sessions, audiovisual presentations, and oral or written recall tests. Other measures might include follow-up questions to assess subject understanding, videotaping or audio-taping of consent interviews, second opinions, use of independent consent observers, interpreter for hearing-impaired subjects, allowing a waiting period before enrollment, or involvement of a trusted family member or friend in the disclosure and decision making process.

Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may subjects be forced or coerced to participate.

3.1 Determining Capacity to Consent

Decisional capacity in the research context has been interpreted by the American Psychiatric Association as requiring:

- Ability to confirm a choice
- Ability to understand relevant information
- Ability to appreciate the situation and its likely consequences
- Ability to manipulate information rationally

For studies that have been approved for enrolling vulnerable populations who may lack capacity to consent, there must be someone who is able to assess capacity of each potential subject to consent. The PI may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time. Additionally, if the reason for lack of capacity is because of mental illness then a psychiatrist or licensed psychologist must confirm this judgment and document in the individual's medical record in a signed and dated progress note.

IRBs should take special care to consider issues such as (1) whether decisionally impaired persons may be suitable subjects for this project; (2) whether, if the study is of more than a minor increase over minimal risk, the study holds out the prospect of direct benefit to the individual in a risk-benefit ratio at least as favorable to the subject as that presented by available alternative approaches; (3) whether the informed consent process can be structured to be appropriate and effective within the limits of the individual's decisional capacity; (4) if surrogate consent will be used, whether assent will also be required; and (5) whether there are

any circumstances under which a surrogate decision maker may enroll a decisional impaired individual in the study over the individual's objection or resistance.

HISTORY:

Effective Date:
Revisions: October, 2018

Responsible Party:

Office of Research Compliance and Assurance