MUSC
Medical University of South Carolina

I. Policy

A. Introduction

Research involving cognitively impaired individuals may only be approved by the IRB when the following conditions apply:

1. Only cognitively impaired persons are suitable as research subjects and competent persons are not suitable for the proposed research. Subjects with impaired decision making capability may not be included in research because they are readily available.

2. The research entails no significant risk or if the research presents some probability of harm, there must be greater probability of direct benefit to the subjects.

B. Assessment

Decision-making capacity/competency assessment of a potential subject who can reasonably be expected to be cognitively impaired must be assessed by a qualified professional independent of the research team. The frequency of this assessment will be appropriate to the population involved in a longitudinal study. It is the responsibility of the investigators to determine and monitor the decision-making capacity of subjects enrolled in research studies. This includes the event when a subject's decision-making capacity changes during the course of the study. The investigator should consider whether consent should be re-obtained from the subject's legal representative. For studies where it is anticipated that subjects may experience diminished decision making capacity, procedures for re-consenting should be detailed in the initial application. Only a legal representative may consent, .i.e. give permission, for a cognitively impaired individual to be enrolled in a research study. If a cognitively impaired adult subject objects to or resists participation in any way at any time, the subject must be immediately withdrawn from the study

C. Memorandum of Understanding

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H.

Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

VA Policy places additional requirements/limitations on research with this population. Details may be found in Appendix D of VHA Handbook 1200.5.

D. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>).

E. ICH – Good Clinical Practice (GCP)

The MUSC IRBs operate in accord with ICH-GCP guidelines only to the extent that they are compatible with FDA and DHHS regulations. CGP standards contained in the ICH document are not regulatory requirements in the United States and vary from FDA and DHHS regulations. As such, the MUSC IRBs do not voluntarily agree to comply with all of the GCP statements unless requested to do so by sponsors as documented in contractual agreements. The MUSC IRBs comply with most aspects of ICH-GCP, and the MUC polices, procedures and forms require investigators to com ploy with most ICH-GCP guidance. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>)

II. Definitions

Definitions for the following terms used in this section may be found in HRPP Program Guide Section 1.3 Definitions of Terms:

A. Cognitively Impaired

B. Competence

C. Legally Authorized Representative or **Legal Representative**

1. **VA Policy**: Legally Authorized Representative. A legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of VHA 1200.05, a legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable state law:

    a) spouse,

    b) adult child (18 years of age or older),

    c) parent,

    d) adult sibling (18 years of age or older),

    e) grandparent, or

    f) adult grandchild (18 years of age or older)

    g) close friend

2. **South Carolina Law**: per § 44-66-30 “The Adult Health Care Consent Act”, the following, in priority order, may make health care decisions for individuals unable to give consent:

    a) Court appointed guardian

    b) Attorney-in-fact with durable power of attorney related to health care decision

    c) Individual authorized by another statue

    d) Spouse – unless legally separated, with provisions

    e) Parent or adult child

    f) Adult sibling, grandparent, adult grandchild

    g) Other relative (by blood or marriage) believed by health care professional, to have close personal relationship

III. Procedures

A. Standard

1. The Principal Investigator will describe the rationale for including this vulnerable population in the research, the method to be used to assess decision-making capacity including the name and qualifications of individual performing the assessment, and the frequency of this assessment in the human subject protections section of the protocol.

2. The Principal Investigator will describe the process of informed consent including who will be asked for consent, i.e. permission, to enroll the subject if the subject is assessed as cognitively impaired.

3. Using the "Special Subject Populations – Cognitively Impaired or Persons Unable to Consent" checklist, the IRB will determine:

   a) if the risk level of participation is reasonable given the intended benefit and possible alternatives,

   b) the appropriateness of the decision-making capacity assessment,

   c) the appropriateness of obtaining surrogate informed consent from a legal representative,

   d) if the available compensation might provide undue influence, and

   e) if any additional protections are required such as the presence of a subject advocate during the consenting process, documented assent of the subject even when lacking decision making capacity, and/or excluding subjects without decision-making capacity from selected procedures of the research protocol.

   These IRB discussions and decisions will be documented in the IRB minutes and communicated to the Principal Investigator.

B. VA Studies

1. An individual is presumed to have decision-making capacity unless any one or more of the following apply:

   a) It has been documented by a qualified practitioner in the individual's medical record in a signed and dated progress

note that the individual lacks capacity to make the decision to participate in the proposed study. ***NOTE:*** *The qualified practitioner may be a member of the research team.*

b) The individual has been ruled incompetent by a court of law.

2. If there is any question as to whether or not a potential adult subject has decision-making capacity, and there is no documentation in the medical record that the individual lacks decision-making capacity, and the individual has not been ruled incompetent by a court of law, the investigator must consult with a qualified practitioner (who may be a member of the research team) about the individual's decision-making capacity before proceeding with the informed consent process.

3. **Temporary or Fluctuating Lack of Decision-Making Capacity.** Individuals, who because of a known condition, are at high risk for temporary (e.g., head trauma) or fluctuating (e.g., schizophrenia) lack of decision-making capacity must be evaluated by a qualified practitioner (who may be a member of the research team), to determine the individual's ability to provide informed consent. This evaluation must be performed as described in the IRB-approved protocol. If the individual is deemed to lack decision-making capacity at the time of their participation in the study, a LAR must provide informed consent. If the subject regains decision-making capacity, the investigator or designee must repeat the informed consent process with the subject, and obtain the subject's permission to continue with the study.

4. The practitioner will explain the proposed research to the prospective participant when feasible.

5. The participant will not be forced or coerced to participate in the research study.

6. The IRB will find and document in the minutes or IRB records that:

a) Only incompetent persons or persons with impaired decision making capacity are suitable as participants.

b) Competent persons are not suitable for the proposed research.

c) The investigator has demonstrated to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as participants.

(1) Incompetent persons or persons with impaired decision-making capacity are not being proposed as participants simply because they are readily available.

(2) The proposed research entails no significant risks, tangible or intangible, or if the research presented some probability of harm, there has to be at least a greater probability of direct benefit to the participant.

(3) The research does not impose a risk of injury, unless the research is intended to benefit that participant and the probability of benefit is greater than the probability of harm.

(4) Procedures are devised to ensure that participants' legally authority representatives are well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity.

(1) (5) Legally authorized representatives are told that their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes could not be determined, what they think is in the incompetent person's best interest.

IV. References

A. Special Subject Populations Checklist - Cognitively Impaired or Persons Unable to Consent