6.10 Persons with Impaired Decision Making Capacity

The requirements in this Section apply to all Research involving persons with mental disabilities or persons with impaired decision-making capacity regardless of funding source.

Research involving persons with impaired decision-making capability may only be approved when the following conditions apply:

1. Only incompetent persons or persons with impaired decision making capacity (as determined by licensed health care professionals who are qualified to make such determinations consistent with the scope of their license) are suitable as Research subjects. Competent persons are not suitable for the proposed Research. The PI must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects. Incompetent persons or persons with impaired decision-making capacity must not be subjects in Research simply because they are readily available.

2. The proposed Research entails no significant risks, tangible or intangible, or if the Research presents some probability of harm, there must be at least a greater probability of direct benefit to the Participant. Incompetent people or persons with impaired decision-making capacity are not to be subjects of Research that imposes a risk of injury, unless that Research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.

3. Procedures have been devised to ensure that Participant’s representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity. Health Agents (appointed under Medical Power of Attorney) and next-of-kin, or Legal Guardians, must be given descriptions of both proposed Research studies and the obligations of the person’s representatives. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject’s wishes cannot be determined, what they think is in the incompetent person’s best interest. In addition and as appropriate, if Assent can be obtained by a subject/potential subject with diminished decision making capacity (versus impaired), then the PI should obtain such Assent. The determination as to whether an individual retains capacity to Assent must be determined by a duly qualified health care provider, consistent with the provider’s scope of licensure.

4. A non-therapeutic clinical trial (i.e., a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written consent document. Non-therapeutic clinical trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

   a. The objectives of the trial cannot be met by means of a trial in subjects who can give consent personally;
   b. The foreseeable risks to the subjects are low.
   c. The negative impact on the subject’s well-being is minimized and low.
   d. The trial is not prohibited by law.
The opinion of the IRB is expressly sought on the inclusion of such subjects, and the written opinion covers this aspect.

Unless an exception is justified, the trial should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in such trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

Regulations & Guidance: AAHRPP II.7.B.

6.10.1 IRB composition

The IRB membership must include at least one member who is an expert in the area of the Research. Consideration may be given to adding another member who is a member of the population, a family member of such a person or a representative of an advocacy group for that population. The IRB may utilize ad hoc members as necessary to ensure appropriate scientific expertise.

6.10.2 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 PI and Research staff must have adequate procedures in place for assessing and ensuring subjects’ capacity, understanding, and informed consent or 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 PI can justify why such assessments would be unnecessary for a particular group.

For Research that poses greater than Minimal Risk, the IRB may require Investigators to use independent and qualified professionals to assess whether potential subjects have the capacity to give voluntary, informed consent. Even in Research involving only Minimal Risk, the IRB may require that the study include a capacity assessment if there are reasons to believe that potential subjects’ capacity may be impaired. It is not necessary to require a formal capacity assessment by an independent professional for all potential Research subjects with mental disorders. See the next Section for details with respect to determining capacity to consent.

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. 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. For subjects with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consenting process with Health Agent may be necessary.

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.

In the event Research Participants become incompetent or impaired in decision making capacity after enrollment, the PI is responsible for notifying HRPO. The PI is responsible for developing a monitoring plan which follows the guidelines outlined above for incompetent and impaired decision making Research Participants.

6.10.3 Determining Capacity to Consent

The majority of studies conducted at the University only allow enrolling subjects who have the capacity to consent. 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.

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

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

A range of professionals and methods may be utilized to assess capacity. In general the consent assessor should be a Researcher or consultant familiar with dementias and qualified to assess and monitor capacity and consent in such subjects on an ongoing basis. The IRB will consider the qualifications of the proposed individual(s) and whether he or she is sufficiently independent of the Research team and/or institution.

A person who has been determined to lack capacity to consent to participate in a Research study must be notified of that determination before permission may be sought from his or her Legally Authorized Representative to enroll that person in the study. If permission is given to enroll such a person in the study, the potential subject must then be notified. If a person objects to participating, this objection should be respected.

6.10.4 Informed Consent and Assent

Whenever the Participants have the capacity to give consent (as determined by licensed health care professionals who are qualified to make such determinations consistent with the scope of their license), informed consent should be obtained and documented in accordance with Section 5 above. When Participants lack the capacity to give consent, PIs may obtain consent from the Legally Authorized Representative of a subject as described below.
A person who is incompetent or has been determined to lack capacity to consent to participate in a Research study should be informed about the trial to the extent compatible with the subject’s understanding and, if possible, the subject should give their Assent to participate, sign and date the written informed consent or a separate Assent Form (TU Form 401). If the person objects to participating, this objection should be heeded.

Both PIs and IRB members must be aware that for some subjects, their decision-making capacity may fluctuate. For subjects with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consenting process with Legally Authorized Representative may be necessary. 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.

6.10.5 Consent by Legally Authorized Representative

The regulations generally require that the Investigator obtain informed consent from subjects. Under appropriate conditions, Investigators also may obtain informed consent from a Legally Authorized Representative of a subject (Legally Authorized Representative).

This policy is designed to protect Human Subjects from exploitation and harm and, at the same time, make it possible to conduct essential Research on problems that are unique to persons who are incompetent, or who have an impaired decision-making capacity.

Legally Authorized Representative may be obtained from a court appointed Legal Guardian of the person or a Health Agent appointed by the person in a Medical Power of Attorney. For example, a subject might have designated an individual to provide consent with regard to health care decisions through a durable power of attorney and have specified that the individual also has the power to make decisions on entry into Research.