Grand Canyon University
Office of Academic Research
College of Doctoral Studies
3300 W. Camelback Road
Phoenix, AZ 85017
Phone: 602-639-7804

Procedure for the Participation of Decisionally Impaired Individuals in Research

I. Applicability: This procedure defines the standards and parameters for the involvement of decisionally impaired individuals in biomedical, behavioral and social science research.

II. Definitions:

Decisionally Impaired: An individual who has a compromised capacity to understand information and make a reasoned decision about participation in research. Such incapacity may be either temporary, permanent or may fluctuate. Decisionally impaired individuals may include women in active labor, individuals under the influence of drugs or alcohol, individuals under extreme emotional distress (i.e., experiencing pain, hearing of a newly diagnosed life threatening or terminal illness for self or loved one, being in the preoccupied condition of anticipating imminent major surgery) or individuals suffering from cognitive disorders.

Decisional impairment as defined throughout this procedure is distinct from legal incompetence. The latter refers to a designation of status that has been adjudicated in a court proceeding. Usually it refers to an inability to manage one or more significant areas of life such as business or monetary affairs. An individual may be decisionally impaired yet legally competent. An individual who is legally designated as incompetent probably will be decisionally impaired in terms of consenting to research.

Independent assessment of capacity to consent: Assessment by an individual who has no interest or affiliation to the study or to the sponsors of the study. The method of assessing capacity to consent ranges from an informal investigator peer evaluation to an independent health care professional utilizing formal instruments of assessment (e.g. dementia rating scales).

Information Sheets: A form used by the Investigator to reinforce certain concepts with the prospective subjects by providing simple, summarized information in a presentation mode best understood by the subject.

Prospective consent with affirmation: Under certain circumstances, and with certain populations or individuals, the investigator may obtain consent in advance of an event which is expected to cause the subject to experience stress and/or pain, and then at the time of the occurrence of the event (during which the research will be conducted), utilize an affirmation form (summary of previous consent) or otherwise seek affirmation (e.g., verbal inquiry) to confirm that the subject recalls the circumstances of the study and still wishes to participate in the study.

Subject Advance Directive: A subject capable of consenting provides consent to participate in a future study or studies during which it is likely that the subject will not be capable of providing consent; a subject advance directive may also be used to allow the subject to name an individual that the subject would like to act as his/her surrogate to provide permission for the subject's continuation in a current study or enrollment in a future study; an advance directive in

either case is especially useful as it serves to document a subject's intentions and philosophy about participating in research. An advance directive may therefore enable the surrogate to be guided by what the subject would have wanted as well as by what the surrogate feels is in the best interests of the subject.

Surrogate Permission: Permission for a subject to participate in research given by a Legally Authorized Representative (LAR) or other appropriate surrogate when an individual is assessed as not capable of providing fully informed and legally effective consent. Federal regulations default the designation of LARs to State law.

Therapeutic Misconception: The belief that research studies are primarily designed to benefit those who enroll in them and that their clinician-investigator is recommending participation as part of their routine care.

III. Procedure Statement:

A. Grand Canyon University (GCU) recognizes that decisionally impaired individuals engaged in research constitute a special class of subjects for which additional protections apply. GCU will ensure that all decisionally impaired individuals enrolled in research conducted at or by this institution will be treated in a manner commensurate with their special status and that their participation in research will be ethical and in compliance with the federal regulations for the protection of human subjects, specifically 45 CFR 46.111(b). ***Research studies specifically designed to include decisionally impaired individuals must have as its goal the development of generalizable knowledge regarding the disease or condition of the subject class.*** GCU will not permit research that targets individuals with mental disorders as subjects when such research can be done with other subjects. All research studies involving decisionally impaired individuals must describe the additional protections in the protocol that is submitted to GCU IRB for review.

B. GCU recognizes that not all individuals who suffer from a cognitive disorder are incapable of providing consent to enroll in a research study. Although the decision-making capacities of decisionally impaired individuals may be in question, an investigator should not reflexively assume that they are unable to provide consent. Rather, investigators should seek to objectively determine whether or not individuals are capable of consent. The purpose of identifying individuals who may be decisionally impaired is not necessarily to exclude them from research, but rather, when appropriate, to seek ways to enable their participation in an ethically acceptable manner that is also compliant with regulatory requirements and guidance as well as organizational policies.

C. No person who has the capacity for consent will be enrolled in a study without his or her informed consent. ***The Principal Investigator (PI) or person obtaining consent will use professional judgment to determine if the potential subject is capable of providing consent.*** The individual who is responsible for determining whether a prospective subject has the capacity to consent must have appropriate expertise necessary to make such a determination. This determination may rely on individual observation of and interaction with the potential subject as well as the opinion of the medical provider or caregiver, when available. The prospective subject should demonstrate competence in relation to the proposed study in order to be judged capable of providing informed consent for that study. In general, an assessment on an individual's capacity to consent should be based on an his/her:

1. Ability to communicate a choice;
2. Ability to understand relevant information;
3. Ability to appreciate the nature of the situation and its likely consequences; and,
4. Ability to manipulate information rationally

D. The individual's abilities can be assessed by discussing the proposed study with her/him and then asking specific questions. It is usually more useful to ask for descriptive answers from prospective subjects rather than a simple yes or no. Such questions could include:

1. Can you tell me what will happen if you agree to take part in this study?
2. How might this study help you?
3. How might this study not help you, or even hurt you?
4. Do you have to be in this study?
5. What would you do if you wanted to leave the study?
6. What will happen if you decide not to be in the study?

E. Similarly, an individual may be considered unable to provide consent if he or she has:

1. An inability to express or communicate a preference or choice (cannot make up his/her mind, is comatose, or has severe psychotic thought disorders, etc.);
2. An inability to understand a situation and its potential consequences as well as the impact of study participation on those circumstances (does not understand that he/she may be hurt or may not be helped or can not distinguish research from treatment); and/or,
3. An inability to provide a logical rationale for participation/no participation in a study (cannot address risk/benefit-related reasons for or against participation in a study or relate the study to personal circumstances.)

F. When potential subjects are capable of making informed decisions about participation, they may accept or decline participation without involvement of any third parties. Any potential or actual subject's objection to enrollment or to continued participation in a research protocol will be heeded in all circumstances.

G. Decisionally impaired subjects may be especially vulnerable to therapeutic misconception. Therefore, investigators should be especially careful to make subjects and their families or caretakers aware of the differences between individualized treatment and research and the correlative roles of clinician and investigator.

H. The method used to assess capacity to consent should be commensurate with the level of risk to the subject and the complexity of the research. A relatively unsophisticated level of assessment may be acceptable for a benign, non-sensitive interview, while a more sophisticated and demanding method would be required for participation in an investigational drug study. Unsophisticated assessments may be as simple as a verbal interaction between the investigator and the prospective subject. More complicated assessments may include administration of a formal assessment instrument or an independent clinical (interview type) assessment, which documents that the prospective subject demonstrated sufficient recall and comprehension. The assessment method may allow for a repeat assessment if the potential subject's decisionally impaired condition has improved or is expected to improve.

I. For research protocols involving subjects who have fluctuating or limited decision-making capacity or prospective incapacity, investigators will establish and maintain ongoing communication with involved caregivers, consistent with the subjects' autonomy and with medical confidentiality. The PI should plan for such change or fluctuations by considering

specific measures such as advance consent or advance directives for subjects with prospective incapacity to consent.

J. In general, individuals who have been determined to lack capacity to consent should not be enrolled in research that is not likely to result in direct benefit to them unless the research presents no more than minimal risk. However, research that presents the subjects with greater than minimal risk may be acceptable if:

1. The risks are justified given the potential benefits of the research (either to the subject or the development of generalizable knowledge to benefit a class of individuals)
2. The research interventions are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
3. A Data and Safety Monitoring Board is convened to monitor the study;
4. When appropriate, provisions are made for surrogate permission or an advanced directive.

K. 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 and the individual's agreement or assent must be obtained; assent being an active affirmation of a desire to participate. Individuals who are able to read and write will participate in the consent process by using an assent form written at a level especially suited to their cognitive ability. Assent procedures will be approved by the IRB.

L. In all cases in which assent is sought from a decisionally impaired subject, the assent discussion will include the following:

1. A simplified description of the purpose of the research, including the risks and benefits (may be presented in an Information sheet);
2. A description of the procedures and interventions to which the subject will be exposed;
3. An explanation of any procedures that may hurt and for how long
4. A statement explaining to the subject that s/he has the right to decide whether or not to participate in the research study;
5. An explanation of the research alternatives; and
6. A question and answer period in which the subject will be encouraged to ask questions about her/his participation in the study.

M. Individuals who are temporarily decisionally impaired due to environmental or other factors (i.e., women in active labor, individuals under the influence of drugs or alcohol, individuals under extreme emotional distress, etc.) may not be enrolled in research until their incapacity has been alleviated. However, in the event that the research is designed to study individuals in just those situations and/or states of mind, Investigators must take care to design the research project so that subjects will be appropriately consented and enrolled.

REVISION DATES:

Adapted with permission from Yale University, Office of Research Administration and Human Research Protection Program, Research Affiliates Policies (2011).