



## Human Research Protection Program

### Policy for Determination of Decisional Capacity to Consent by Adult Persons for Human Subject Research

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#### I. BACKGROUND

While Department of Health and Human Services (DHHS) regulations do not provide specific requirements for research involving individuals with diminished functional abilities or who lack the capacity to consent, persons signing consent forms indicating their consent to participate in a specific research study must have adequate decision-making capacity to do so.

Research involving participants with diminished functional abilities should only be proposed when it cannot reasonably be conducted without their participation or when research presents potential benefits from which participants with diminished functional abilities should not be *per se* excluded, and should never be justified based on their availability or the convenience for the researcher. Importantly, excluding persons who may have impaired consent capacity from participation in clinical research aimed at addressing diseases, disorders, conditions and injuries of the brain and body that can affect cognition, mental acuity, awareness, and decision-making capacity can significantly delay attempts to answer important scientific questions that could lead to new treatments and better diagnostic, predictive, and preventive strategies. Enrolling participants with such disorders is crucial to the development of new treatments and diagnostic and preventive strategies, but may require application of methods to enhance a prospective participant's ability to provide informed consent or engagement of a [legally authorized representative](#) (LAR).

#### II. PURPOSE

The purpose of this Policy is to provide Brown researchers with guidelines for assessing decisional capacity in prospective adult participants in human research applications that are greater than minimal risk and to establish who may serve as an LAR for research purposes. This guidance applies not only to primary conditions of cognitive impairment (i.e., dementia, psychosis), but also to conditions in which participants might reasonably be expected to have cognitive impairments as a consequence of severe pain, anxiety or

confusion. Excluded from this guidance document are minors, as there are specific consent/assent requirements for that vulnerable population.

### III. SCOPE

Explicit assessment of decisional capacity in adult participants is required for applications in which the following criteria apply:

- (a) Any study involving “[greater than minimal risk](#)” (as defined by federal guidelines on research involving human participants), and;
- (b) The application is specifically intended for a study population in which *at least some* participants can be reasonably expected to have diminished decision-making capacity. In such applications, either all research participants may be assessed for decisional capacity, or there may be a two-step process. The first step may involve a quick evaluation of the need for a detailed assessment. For example, the participant may be asked: “Can you tell me what this study is about?” An accurate response to this question by the participant may eliminate the necessity for further evaluation of decisional capacity. Procedures to conduct a detailed assessment of decisional capacity are outlined below.

**Special Requirements:** Additional special requirements may apply to research projects enrolling adult participants with potentially impaired decisional capacity depending on the research funding source and the facility or facilities at which the research will be conducted. For example, the Department of Defense and Veterans’ Administration have policies that may supplement or differ from those specified in this guidance document. Investigators should address all applicable policies in preparing IRB applications that may involve adult participants with potentially impaired decisional capacity.

### IV. DEFINITIONS

**A. Informed Consent.** Informed consent has four essential elements or features:

- (1) The consent is given in the absence of coercion or undue influence;
- (2) The potential participant is provided with all the information (in language understandable to him or her) relevant to making a meaningful decision whether or not to participate (or to continue participating);
- (3) The potential participant has a level of decision-making capacity needed to make a meaningful choice about whether or not to participate in the study; and
- (4) The potential participant must perform a physical action (*i.e.*, speaking, checking a box, answering questions, writing, etc.) to indicate that consent has been given.

**B. Decision-Making Capacity.** The phrase “decision-making capacity” refers to a prospective participant’s ability to make a meaningful decision about whether or not to participate. It is generally thought to include at least the following four elements:

- (1) Understanding, *i.e., the ability to comprehend the disclosed information about the nature and purpose of the study, the procedures involved, as well as the risks and benefits of participating versus not participating;*
- (2) Appreciation, *i.e., the ability to appreciate the significance of the disclosed information and the potential risks and benefits for one’s own situation and condition;*
- (3) Reasoning, *i.e., the ability to engage in a reasoning process about the risks and benefits of participating versus alternatives, and;*
- (4) Expression, *i.e., the ability to express a choice about whether or not to participate.*

“Decision-making capacity” is not necessarily synonymous with the legal concept of “competence.” Incompetence is a legal determination made by a court of law, the result of which is that an individual so judged is not legally able to carry out certain decisions (those decisions would not be legally effective). Legal incompetence may be all-encompassing, or it may be more narrowly confined to a certain category of decisions. For example, where a court is called upon to authorize a specific decision-maker, such as with court-appointed guardians, the court may determine that a particular individual requires legal authorized representation for a specific purpose (*i.e., health care, financial*) but not for others. In the same way, an individual with, for example, memory impairment, may retain sufficient decision-making capacity to make decisions regarding research participation. Accordingly, the assessment of decision-making capacity should focus on the capacity to consent to the proposed research participation, as described in more detail below.

## **V. PROCEDURES FOR ASSESSING DECISION-MAKING CAPACITY**

Decision-making capacity is study-specific and situation-specific. A participant’s capacity to understand, appreciate, reason with, and express a choice about a specific application for which they are consenting to be enrolled must be determined, and may fluctuate over time.

### **A. Who can assess decision-making capacity?**

Cognitive tests and competence assessment instruments alone should not provide the basis of the evaluator’s determination regarding a participant’s capacity to consent, and should be used to supplement or support an evaluator’s expert judgment. It is therefore recommended that the Principal Investigator (PI) conduct the assessment. A research assistant or other research personnel very familiar with the study application may administer standardized scales (on which they are trained and have demonstrated

competence), but a final determination regarding the participant's capacity to consent should be made in conjunction with the PI.

## **B. Methods to assist with evaluators' determination of decision-making capacity**

Methods to assist with evaluators' determinations<sup>1</sup> may include:

- (1) Conducting clinical interviews with prospective participants and asking them to describe aspects of the study;
- (2) Using standard psychological and neuropsychological screening tests; and
- (3) Utilizing a formal instrument for assessing capacity to consent in clinical research.

Examples of existing cognitive tests include the *Mini-mental State Evaluation* (MMSE) and the *Montreal Cognitive Assessment* (MoCa). Comprehensive capacity assessment instruments that can be tailored to the specific study application include the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR; Appelbaum and Grisso [1995]) and the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC).<sup>2</sup>

If the PI wishes to develop his/her own evaluation application, the Brown IRB requires that the participant demonstrate capacity to understand the following critical elements of the informed consent (**yes/no questions are insufficient**). The evaluation application may include a discussion of the following consent elements followed by a series of questions to assess the person's capacity to understand:

- Nature of the subject matter being studied
- Procedures involved
- Time required
- Voluntary nature of participation
- Consequences of withdrawing from study
- Possible risks and benefits of participation
- Confidentiality
- Whom to call with any questions about the study

For participants who score less than perfect on the initial presentation, educational procedures may be employed to raise their understanding to sufficient levels for them to make a meaningful choice about participating. Such procedures may include simple repetition of the relevant information in the consent form or more detailed explanations

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<sup>1</sup> When seeking to apply cognitive screening tests and competence assessments, researchers should consult scholarly reviews to ensure that the chosen test or instrument is effective and appropriate to the study.

<sup>2</sup> Jeste DV, Palmer BW, Appelbaum PS, Golshan S, Glorioso D, Dunn LB, Kim K, Meeks T, Kraemer HC. (2007) A New Brief Instrument for Assessing Decisional Capacity for Clinical Research. *Arch Gen Psychiatry*. 64(8):966-974. Full text available at <http://jamanetwork.com/journals/jamapsychiatry/fullarticle/482397>

of items that the participant has difficulty understanding. Note that some of these approaches (i.e., using an evaluation of understanding to test decisional capacity) may also be useful for all participants, even those with demonstrated decisional capacity, to ensure that a meaningful consent has occurred.

### **C. Efforts to support prospective participants' ability to consent**

When feasible, researchers should make efforts to support or enhance prospective participants' ability to consent and conduct the consent process in an environment in which the participant is comfortable. Some individuals who are not capable of consenting under routine consenting procedures might be capable when special measures are adopted, such as:

- 1) Designing a stepwise consent process, which involves a waiting period between each phase of the process: capacity assessment, initial presentation of information, and obtaining consent;<sup>3</sup>
- 2) Enhanced presentation of consent information during initial presentation and/or immediately prior to obtaining consent, including repetition of information (especially misunderstood information);<sup>4</sup>
- 3) Oral and written presentation of information, and, when appropriate, multi-media presentation of information;<sup>5</sup>
- 4) Interactive questioning during the consent process has been shown to increase post-consent participant understanding, and has the added benefits of highlighting important elements for the participant to focus on, ensuring understanding of earlier material to allow understanding of subsequent information, and assessing participant understanding during the process to allow for appropriate explanation throughout the process.<sup>6</sup>

### **D. What if a prospective participant fails to demonstrate adequate decision-making capacity?**

If a prospective participant fails to demonstrate adequate decision-making capacity, then a [legally authorized representative](#) (LAR) may provide consent on behalf of the participant. Federal regulations that govern research involving human subjects define an LAR as an individual or 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. If there is no applicable law addressing this issue, legally

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<sup>3</sup> Eyler LT, Jeste DV. (2006) Enhancing the Informed Consent Process: A Conceptual Overview. *Behav Sci Law*. 24:553-68.

<sup>4</sup> Palmer BW, Jeste DV. (2006) Relationship of Individual Cognitive Abilities to Specific Components of Decisional Capacity Among Middle-Aged and Older Patients with Schizophrenia. *Schizophrenia Bulletin*.

<sup>5</sup> Eyler LT, Jeste DV. (2006)

<sup>6</sup> Eyler LT, et al. (2005) A Preliminary Study of Interactive Questioning Methods to Assess and Improve Understanding of Informed Consent Among Patients with Schizophrenia. *Schizophrenia Research*. 75: 193-8.

authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. Laws regarding who may serve as an LAR vary from state to state, therefore it is imperative that the investigator take into account local context when developing an application in which it is anticipated that the study population may not be able to provide consent at the time of initial enrollment, or where it is reasonable to expect that decision-making capacity will decline during the course of the study.

Rhode Island does not have a generally applicable law that proscribes who can serve as an LAR in either the treatment or research context. In some circumstances (such as consenting to an invasive medical treatment for a developmentally disabled adult), specific Rhode Island statutes may apply.<sup>7</sup> Notwithstanding the lack of directly applicable state law, it is the policy of Brown that the following individuals may serve as an LAR for an adult participant who lacks capacity to consent, in order of priority:

- 1) A court-appointed legal guardian with full guardianship authority (if a prospective participant has a court-appointed limited guardian, it may be necessary to consult with the [Office of General Counsel](#) to determine whether the guardian is authorized to consent on behalf of the prospective participant);
- 2) A health care agent appointed by the individual in a Durable Power of Attorney for Health Care;
- 3) Spouse;
- 4) Any adult child;
- 5) Either parent; or
- 6) Any adult sibling.

In the absence of any other person authorized to provide consent above, the IRB may consider allowing another relative or an adult close friend of the prospective participant to provide consent, provided that the relative or close friend has exhibited special care and concern for the individual, is generally familiar with the individual's views and desires, and is willing and able to act in the individual's best interest.

If an LAR is used to make a decision to enroll a decisionally impaired adult into a research study, the LAR's decision should reflect the wishes and values of the prospective participant to the extent they are known or can be determined. The greater the risks posed by the research, the more evidence of the prospective participant's desire to participate should be required. If the prospective participant's wishes and values are not known, the LAR should act in the prospective participant's best interest given the anticipated risks and benefits of participation in the research.

Even when an LAR provides consent on behalf of a decisionally impaired participant, whenever feasible, the investigator must also explain the proposed research to the

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<sup>7</sup> See RI ST § 40.1-26-3(18).

prospective research participant and seek their assent. Although unable to provide informed consent, some persons may resist participating in a research application approved by an LAR. Under no circumstances may a participant be forced or coerced to participate in a research study even if the LAR has provided consent.

#### **E. Reassessing decision-making capacity throughout the course of a study**

Consent capacity can be affected by disorders with progressive or fluctuating courses. In studies where a participant's cognitive condition is reasonably expected to deteriorate or fluctuate throughout the course of the study, the PI should describe in the IRB application how consent capacity (and, as appropriate, strategies for consent enhancement) will be conducted. Intervals within which decisional capacity will be re-assessed should be study-specific (i.e., employed at appropriate phases of a long-term study), and possibly participant-specific depending on the circumstances. For individuals with conditions that bring about fluctuating levels of consent capacity, it is important to consider the timing of the assessment and consent; it may make sense to time the initial consent carefully to avoid periods when prospective participants may be experiencing heightened impairment. In all cases, respecting a participant's right to withdraw from a research study is a continuation of the initial consent process, and consideration should be given to ensuring that diminished capacity does not limit this right.

In the event that a participant unexpectedly experiences a substantial impairment to his or her functional abilities that is not foreseeably temporary, researchers should notify the IRB. In such cases the IRB will determine whether it is necessary to re-evaluate the participant's capacity to consent to determine whether the participant who has lost the capacity to consent is permitted to remain in the study.

If the participant is determined to be incapable of consenting and is not likely to regain the capacity to consent in the near future, but the convened IRB determines that his or her ongoing participation is reasonable, researchers should obtain his/her assent to continue enrollment (if feasible) and must obtain the consent of an LAR, as soon as possible.

### **VI. IRB APPLICATION & DOCUMENTATION REQUIREMENTS**

Applications submitted to the IRB that propose recruitment of participants with potentially diminished decisional capacity must describe how an initial and, as applicable, ongoing evaluation of decision-making capacity will be conducted. If a standardized decision-making capacity instrument is to be used, a copy of the instrument, tailored to the specific research, must be included with the application. If a post-test/questionnaire will be employed, a copy of the questionnaire to be used should be included. If another method is developed, copies of materials relevant to that method should be included with the application. The PI should also describe who (by role and relevant training/qualifications, *not by name*) will administer any cognitive tests and/or

capacity assessment instruments, and how the PI will engage in making a final determination regarding a prospective participant's capacity to consent.

For studies that fall under this policy, any required decision-making capacity determination should be documented in each relevant participant's research file. This may be done by including a copy of the relevant materials in the research file, (i.e., a copy of the record form from the standardized instrument, including the participant's responses to each item) and a copy of any post-test documents with the participant's answers to each item. The need for investigators to document the specific procedure of determining capacity is proportional (1) to the degree of impairment of the proposed study population as well as (2) the degree of risk posed to the participants of the proposed research.