**Supplement Form I**

**Research Involving Subjects with Impaired Decision Making Capacity**

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| --- | --- |
| **PI Name:** | **Date** |
| IRB# & Title: | |

Complete this form if your research will or may include participation of subjects without or with impaired decision making capacity. This includes subjects with temporary or permanent incapacity or with fluctuating or diminishing capacity.

1. **Subjects with Impaired Decision Making Capacity**
   1. **Describe the root causes or conditions that led to subjects having impaired capacity to provide informed consent for participation in this research (e.g., unconscious ICU patient, Alzheimer’s, stroke, chemically induced, physical injury, etc.):**

* 1. **Indicate the expected nature/duration of incapacity (check all that apply):**

Temporary

Permanent

Diminishing

Fluctuating

Other, describe:

* 1. **Explain why this research could not be accomplished without including subjects with impaired decision making capacity:**

Protocol aims cannot be met without inclusion of subjects with impaired decisions making capacity.

Other, Explain:

* 1. **Will the subject population include subjects who are institutionalized?**

Yes  No

If yes, describe the setting and provide documentation of permission from the institution:

* 1. **Will the subject population include subjects under the custody or care of the court or court appointed guardians?**

Yes  No

If yes, explain the reasons for custody and the steps that will or have been taken to ensure that inclusion of the subjects is permissible and appropriate:

1. **Risk/Benefit**
   1. **Are the risks to subjects in this research no more than minimal?**

Yes  No

*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

* 1. **Indicate if the research includes any of the following (check all that apply):**

Interactions with subjects

Interventions or procedures (for the research)

Manipulations of the subjects’ environment

Observation of subjects

Deception

Review of private information or records

Review of mental health records

Review of psychotherapy notes or records

**Note**: *Separate HIPAA authorization is required for use of psychotherapy notes in research.*

* 1. **If the research involves greater than minimal risk to subjects, does the research offer the prospect of direct benefits to the individual subjects?**

Yes  No  NA

If yes, describe:

1. **Consent** 
   1. **Is a waiver of consent being sought for some or all subjects?**

Yes, *complete Supplement E to request a waiver of consent*

No, answer the following:

* 1. **Describe the procedures to be used to determine the individual subject’s capacity to provide consent** (e.g., assessment by Principal Investigator, evaluation by independent practitioner, use of University of California San Diego Brief Assessment of Capacity to Consent (UBACC), use of MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), etc.):

**NOTE:** *Unless obvious (e.g. person is unconscious),**the decision-making capacity of individual subjects should not be assumed because of a condition or diagnosis. When at risk for impaired decision making capacity or when capacity is in question, the capacity of individual subjects to provide consent for research should be determined through the use of a standardized measure or evaluation by a qualified professional.*

* 1. **When it has been determined that a subject lacks the capacity to provide consent:**
     1. Describe who may provide surrogate consent and how their qualification to do so will be determined (i.e., who may serve as Legally Authorized Representative (LAR))?

**Note:***See NJH SOP 15.3 for the definition of who is considered a LAR.*

* + 1. How the LAR’s role and responsibilities as surrogate decision-maker will be explained (e.g., asked to make the decision that they believe the subject would want, ability to withdraw, etc.) and any procedures that the investigator may use to evaluate their understanding and ability to fulfill their role?

* 1. **If capacity may fluctuate or diminish over the course of the research, describe any plans and procedures to re-evaluate capacity** (e.g., will capacity be assessed at each research visit, at established intervals, when certain signs or symptoms emerge, etc.)**:**

* 1. **If capacity may be regained over the course of the research, describe any plans or procedures to explain the research and to obtain consent for ongoing participation:**

1. **Assent**
   1. **Will subjects be asked to provide assent to participate?**

Yes, answer the questions below

No, explain why:

* + 1. Describe the proposed assent process:

* + 1. What will happen if the subject does not provide assent or expresses unwillingness to participate or to have a research exam or procedure?

* + 1. How will assent be documented? *(If assent will be documented on an assent form, include a copy of the form with the submission.)*

* + 1. Describe any plans and procedures to obtain ongoing assent (e.g., will assent be established at each research visit or procedure, at established intervals, etc.?):