Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email OR-Web-Support@uci.edu for assistance.

 INSTRUCTIONS

This information is necessary for the IRB to determine if the criteria for approval at [45 CFR 46.111(b)](https://www.ecfr.gov/current/title-45/part-46/section-46.111#p-46.111(b)) and [21 CFR 56.111(b)](https://​/%E2%80%8Bwww.ecfr.gov/%E2%80%8Bcurrent/%E2%80%8Btitle-21/%E2%80%8Bpart-56/%E2%80%8Bsection-56.111#p-56.111(b)) are satisfied for adults with impaired decision-making capacity. Additionally, the information collected assists the IRB in following [UCOP guidance on surrogate consent](https://researchmemosapi.ucop.edu/index.php/site/document?memo=UlBBQy0yMS0wMQ==&doc=3789) for research conducted in California. For more information, visit: [Vulnerable Populations](https://research.uci.edu/human-research-protections/subject-enrollment/vulnerable-populations/) and [Use of Surrogate Consent in Research](https://research.uci.edu/human-research-protections/subject-enrollment/informed-consent/use-of-surrogate-consent-in-research/).

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

 1. STUDY INFORMATION

**Short Title:** Specify the short study title.

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| Click or tap here to enter text. |

 2. INCLUSION OF ADULTS WITH IMPAIRED DECISION-MAKING CAPACITY

**Population:** Specify the populations included in the research.

☐​ Cognitively Impaired

☐​ Medically Incapacitated

**Rationale:** Provide a compelling and scientifically sound rationale for inclusion of this population.

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| Click or tap here to enter text. |

**Decision-Making Capacity:**

1. Describe in detail the plan for evaluating the subjects decision-making capacity to provide informed consent.
2. Specify who will be performing the decision-making capacity evaluation. Provide the credentials, experience, and expertise of the individual(s) performing the evaluation.
3. Explain if it reasonable to expect that during the study subjects may lose their capacity to consent or their ability to withdraw consent (e.g., research involves repeated interactions over a period of time, research involves administration of or withdrawal of antipsychotic drug).
	1. If participants may lose their capacity to consent, address the following:
		1. Describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.
		2. Describe what provisions will be put in place to protect the participant’s rights (e.g., ongoing informed consent, use of surrogate consent).

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| Click or tap here to enter text. |

 3. USE OF SURROGATE

[ ]  *This section is not applicable; end of form.*

**Surrogate consent may be considered only in research studies relating to the cognitive impairment, lack of capacity or serious or life-threatening disease and conditions of the research subjects.**

**Subject Cohort:** If the research includes multiple subject cohorts/populations, specify if surrogate consent will be obtained for all subject cohorts/populations.

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| Click or tap here to enter text. |

**Assent:**

1. Describe whether assent will be required of all, some, or none of the subjects.
	1. If some, indicate which subjects will be required to assent and which will not (and why not).
2. Describe any process that will be used to obtain and document assent from the subjects.
3. Describe how a subject’s objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.
4. Describe how a subject’s objection or resistance (including non-verbal) to the use of surrogate consent will be identified, and what will occur in response.

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| Click or tap here to enter text. |

**Plan for Surrogate Consent:** Describe a plan that outlines the sequence of steps that will be employed by the study team to acquire and document surrogate consent provided by a legally authorized representative.

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| Click or tap here to enter text. |