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| **Study Title:** |  |

Complete this form for research involving adults with [impaired decision-making ability](https://www.uthscsa.edu/vpr/services/glossary#Impaired-Decision-Making-Ability).

The information provided on this form will be used by the IRB to determine whether it is appropriate to include adults who are unable to provide consent and that sufficient safeguards are provided to protect the subjects. For additional information, review the IRB policy Research Involving Individuals with Impaired Decision-Making Ability.

This form contains three sections, the following questions are provided to determine if any are not applicable.

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| Will anyadults with **impaired decision-making ability** also be [**institutionalized**](https://www.uthscsa.edu/vpr/services/glossary#Institutionalized)? | |
| |  |  | | --- | --- | | |  | | --- | |  | | | No (mark Section B of this form as not applicable) |
| |  |  | | --- | --- | | |  | | --- | |  | | | Yes (complete Section B) |

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| **Section A – Justification for including adults with impaired decision making ability** |

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| **1**. Why are adults with **impaired decision-making ability** suitable to participate in this research? Provide compelling justification for inclusion of impaired decision-making ability subjects that mitigate any additional risk of their inclusion (Could the study be conducted without them?). NOTE: Investigators must address in the protocol how they determine when surrogate consent will be required. |
| This population is appropriate because…the additional risk of their inclusion is mitigated by the fact that…  The study could not be conducted without them because…  Competent subjects cannot be used because… |

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| **2**. Who will determine individuals’ competency to consent? Identify them by name below and describe the criteria to be used in determining competency (e.g., use of standardized measurements, consults with another qualified professional, etc.). |
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| **3. Address procedures you will use to ensure the subject’s representative is informed regarding his/her role and obligation to protect the person with impaired decision-making ability.** This is someone who can be reasonably assumed to have the subject’s best interest in mind and can assist the subject in navigating the consent and research process. **Describe how individuals will be identified to serve** in this capacity and how you will inform them of their role and obligation. If this request is not appropriate for this study, justify waiving it. | | | | |
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| **3**. Is it reasonable to expect that during the course of the research, subjects with capacity to consent **may lose the capacity to consent**, or that subjects without the capacity to consent may **vary in their ability to assent** or their ability to withdraw? | | | | |
|  | |  | | --- | |  | | **Yes** - If yes, answer 3(a) and (b) | |  | | --- | |  | | **No** - If no, skip to Q. #4 |
|  | (**a**) Describe the process for re-consent, assent and re-[assent](https://www.uthscsa.edu/vpr/services/glossary#Assent), or reassessment of willingness to continue participation. | | | |
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|  | (**b**) Describe what provisions are in place to protect the subjects’ rights in the event they lose their capacity to consent or their capacity to withdraw during the course of the research. (e.g., power of attorney, consent a caregiver as well, etc.). | | | |
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| **4**. Explain how you will identify who is authorized to **give legally valid consent** on behalf of any individual(s) determined to be incapable of consenting on their own behalf. [Guidance related to legally effective informed consent under HHS, FDA, VA regulations and Texas state law](https://www.uthscsa.edu/sites/default/files/Services/forms/irbconsentpolicyattachment1.pdf) |
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| **5**. Explain the criteria you will use for determining when [assent](https://www.uthscsa.edu/vpr/services/glossary#Assent) is required for subjects who have impaired decision-making ability.. |
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| **6**. Explain what methods will be used for evaluating [dissent](https://www.uthscsa.edu/vpr/services/glossary#Dissent) (e.g., description of behaviors that would indicate individual does not want to participate (such as moving away, certain facial expressions, head movements, etc…). |
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| **7**. Will the research interfere with current therapy or medications? | | | | |
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|  | If yes, describe what the changes may entail (i.e., if the subject will be removed from routine drugs/treatments, wash out periods, etc.) and the potential risks related to these changes. | | | |
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| **Section B – Justification for including institutionalized adults** | |
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| **1**. Justify the use of institutionalized individuals and explain why non-institutionalized individuals can not be substituted. |
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| **2**. Provide a description of the research as it pertains to institutionalization. Include whether the research plan involves the manipulation of the institutionalized individuals’ routine schedule, rewards for participation, etc. |
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| **Section C –** **Local Investigator will enroll subjects Outside the state of Texas** | |
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| **1**. Provide information regarding the state definition of legally authorized representative, child, decisionally-impaired, or guardian, as applicable to the research and to the federal definitions. [If the research is to be conducted in more than one state outside of Texas, provide this information for each state.]. |
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