|  |  |
| --- | --- |
| **IRB Meeting Date :** Click or tap to enter a date. | **eBridge #:** Click or tap here to enter text. |
| **Date of EXR Review:** Click or tap to enter a date. |
| **Principal Investigator:** Click or tap here to enter text. | **Reviewer Name:** Click or tap here to enter text. |

This checklist should be used with the *New Protocol Reviewer Checklist* for projects which request the inclusion of subjects with decreased decisional ability. IRB Committee Members should apply the criteria outlined within the *IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*

1. **Can the research objectives be satisfied without enrolling decisionally impaired subjects?**

Yes  No  Comments: Click or tap here to enter text.

1. **Does the investigator propose to assess the decisional ability of subjects prior to project enrollment?** Yes  No  Comments: Click or tap here to enter text.
2. **Does the investigator clearly describe a plan to identify the LAR for a subject with decreased decisional ability?** Yes  No  Comments: Click or tap here to enter text.
3. **Does the investigator propose to monitor the decisional ability of subjects over the course of the project?** Yes  No  Comments: Click or tap here to enter text.
4. **Does the project pose greater than minimal risk (this includes if the risk is a minor increase over minimal risk?)** Yes  No  Comments: Click or tap here to enter text.
5. **If the project poses greater than minimal risk, does the project pose a prospect of direct benefits to subjects (if so, specify those benefits)?** Yes  No  N/A
6. Please cite the identified benefits: Click or tap here to enter text.
7. **If the project poses greater than minimal risk, is the project likely to yield “generalizable knowledge about the subjects’ disorder or condition which is of VITAL importance for the understanding or amelioration of the disorder/condition (if so, specify why the knowledge may be vital)?**

Yes  No  N/A

1. Please cite the areas of vital knowledge & why the knowledge is vital: Click or tap here to enter text.
2. **Are there appropriate safeguards for decisionally impaired subjects?**

Yes  No

|  |
| --- |
| **Reviewer Comments** |
| Click or tap here to enter text. |

Reviewer Name:Click or tap here to enter text. Date: Click or tap to enter a date.