## 

## Institutional Review Board

## SUPPLEMENT D – COGNITIVELY IMPAIRED SUBJECTS

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| **Principal Investigator:** | Click here to enter text. |
| Study Title: | Click here to enter text. |

Please complete if your research involves individuals who are cognitively impaired or have other reductions in mental functions.

## Cognitively Impaired Subjects

* 1. Describe the cognitively impaired subjects to be included in this research:

Click here to enter text.

b. Explain why these subjects need to be included in this research:

Click here to enter text.

c. Are any of these subjects institutionalized? **Yes No**

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

Click here to enter text.

## CCC-UPR Institutional Review Board

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1. **Risk/Benefit**
   1. Are the risks to subjects in this research no more than minimal? **Yes No**
   2. If the research involves greater than minimal risk to subjects, are there direct benefits to the individual subjects? **Yes No**

If yes, describe:

Click here to enter text.

## Consent and Assent

* 1. Describe the procedures to be used to determine the individual subject’s capacity to provide consent:

Click here to enter text.

Note: The decision-making capacity of individual subjects should not be assumed because of a condition or diagnosis. The decision-making capacity of individual subjects should be determined through the use of a standardized measure or by consultation with a qualified professional.

* 1. For subjects where it has been determined that they lack the capacity to give consent, describe the provisions for obtaining consent from the subjects’ legally authorized representative:

Click here to enter text.

* 1. Describe how the assent of the subjects will be obtained and documented. Attach copies of all assent forms, if any:

Click here to enter text.