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| Study ID |  | PI |  |  |

Type of Research:  Medical  Non-Medical

The IRB will require the following for its decision-making:

A complete and standardized evaluation of the capacity of the subject to understand the consent process and sign an informed consent. The evaluation method should be one that has been referenced for use in the particular field of medicine. The explicit method for the evaluation should be provided to the IRB, and results should be documented in the medical and research record.

Why does the study meet this criterion?

When appropriate, the IRB would allow a legally authorized representative or family member to sign proxy informed consent, if that person is authorized to make decisions about medical care for the subject. The investigator should document in the medical and research record who is legally authorized to make medical decisions.

Why does the study meet this criterion?

Whenever possible, the subject should be approached about research assent; that assent form and process should be based on the measured capacity of the subject. If used, the assent process should be presented to the IRB. The wishes of the subject should be respected regardless of proxy consent.

Why does the study meet this criterion?

The investigator should provide detailed information of the risks and benefits of the research to the proxy and the subject (if the subject can possibly understand). The protocol should be based on good science and sound research design with the potential for significant beneficial results.

Why does the study meet this criterion?

Whether the vulnerable population is the one that will receive primary benefit from the research. Conversely, the research should not be conducted in a vulnerable population if it can be done in competent subjects.

Why does the study meet this criterion?

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| IRB determination made by: | | | | |
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| Full board | Name of individual completing this form: |  | Meeting date |  |
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