Researcher’s Certification of Consent and Authorization*

I have:

___ Conducted the informed consent and/or authorization discussion in private, or only in the presence of those people that the potential subject wanted to hear the discussion.

___ N/A

___ Noted that the potential subject is fluent in English or that the subject (check all that apply):

___ Signed form written in own language: ________________________________

___ Was assisted by study personnel fluent in ______________________________

___ Was assisted by a professional medical interpreter.

___ Was not enrolled because refused offer of professional medical interpreter.

___ Was not enrolled because study restricted to those fluent in English.

___ Read the Informed Consent and/or the Authorization Document with subjects who do not choose to read the document on their own. ___ N/A

___ Verified an adequate level of comprehension by:
Asking the potential research subject to restate his/her understanding of the research.

___ Goal of the Research and Protocol

• “Tell me in your own words about the goal of this research and what will happen to you if you agree to be in this study.

___ Benefits and Compensation

• “What do you expect to gain by taking part in this research?”

___ Risks

• “What risks would you be taking if you joined this study?”

___ Voluntariness

• “What do you think will happen to you if you refuse to be in this study?”

* This form is designed for minimal risk, noninterventional research only.

Discontinuing Participation

- “What should you do if you agree to be in the study but later change your mind?”
- “What will happen to information already gathered if you change your mind?”

Privacy

- “Who will be able to see the information you give us?”

Contact Information

- “What should you do if you have any questions or concerns about this study?”

Reviewed any misinformation (e.g., “Let's talk about the goal of the study again because I think I have not explained the project clearly.”).

Asked the potential research subject to restate concepts not clearly understood.

Repeated this process until the potential research subject was able to exhibit comprehension.

Encouraged the potential research subject to ask questions.

Provided a copy of the Informed Consent and/or Authorization Document.

If all above items are not checked, note exceptions here:

______________________________________________________________________________
______________________________________________________________________________

Adequate level of Comprehension Confirmed

Not eligible due to lack of comprehension

Signature

Date

Name (Print)

Title