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.

The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research. September 2009, Agency for Healthcare Research and Quality, Rockville, MD. AHRQ Pub. No. 09-0089-EF. http://www.ahrq.gov/fund/informedconsent/.

____ **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

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