INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If this study constitutes an applicable drug or applicable device clinical trial as defined by the Food and Drug Administration Amendments Act of 2007, the following statement applies:

A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact ______________ at ____________ any time you have questions about the research.

You may contact the Beth Israel Deaconess Medical Center Human Subjects Protection Office at 617-975-8500 if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.
Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor)

Date

Relationship of Legally Authorized Representative to Subject

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject’s language, the researcher’s presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter/witness: ________________________________

Printed name of Interpreter/witness: ________________________________

Date: ____________________