

Principal Investigator: _____
Application No.: _____
Study Title: _____

Consent to Participate in Research

You are being asked to participate in a research study. Before you agree, you must first be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want to join the study.

After presenting the summary, the study team will provide you with additional details about the study which must include:

- (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 study team 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 how many people will be in the study.
- (vii) For clinical trials: 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 (name) _____ at (phone number) _____ any time you have questions about the research.

You may contact (name) _____ at (phone number) _____ 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 participant

Date/Time

Signature of interpreter/witness

Date/Time

