

Consent to Participate in a Research Study

Subject's Full Name: _____ **IRB ID #:** _____

Principal Investigator's Name: _____ **Phone Number:** _____

A University of Iowa investigator is inviting you to participate in a research study.

Before you decide whether to participate in this research study, the investigator must tell you:

1. the purpose of the research study
2. the study procedures
3. how long your involvement in the research will last
4. any procedures that are experimental
5. any reasonably foreseeable risks, discomforts, and benefits of the research
6. any potentially beneficial alternative procedures or treatments
7. how the confidentiality of your data will be maintained

Where applicable, the investigator must also tell you about:

1. any available compensation or medical treatment if injury occurs
2. the possibility of unforeseeable risks
3. circumstances when the investigator may stop your participation
4. any added costs to you
5. what happens if you decide to stop participating
6. new findings that may affect your willingness to participate
7. how many people will be in the study

A description of this research study may be available at www.ClinicalTrials.gov, as required by U.S. law for some studies. This website will not include information that can identify you. At most, the website will include a summary of the research results. You can search this website at any time. The investigator will tell you if a description of this study is available on the website.

If this research study involves the access or creation of Protected Health Information (PHI), the investigator must give you a copy of the University of Iowa Health Care *Privacy Notice* in your chosen language. If you choose to be in this study, you will sign the University of Iowa Health Care *Receipt of Privacy Notice Form* before you begin participation in this study and before any PHI is accessed or created. The investigator will provide these forms to you if the study involves PHI.

If you agree to participate, the investigator must give you a copy of this signed document in your chosen language and a copy of the IRB-approved full Informed Consent Document for this study, which is a summary of the research written in English.

Any time you have questions about the research, you may contact the Principal Investigator at the phone number listed above.

If you have questions or concerns about your rights as a research participant or about what to do if you are injured from participating in the research, contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242, (319) 335-6564, or e-mail irb@uiowa.edu.

Your participation in this research is voluntary, and you will not be punished or lose benefits if you refuse to participate or decide to stop participating at any time.

Participant

Your signature below means that a translator described the research study, including the above information, to you orally, the investigator has answered your questions, and that you voluntarily agree to participate in the research study.

Participant Printed Name _____

Participant Signature _____ **Date** _____

Translator

I affirm that I am fluent in both English and the following language, _____, and have orally presented the information in the English consent document to the 'Participant' listed above and answered any questions.

Translator Printed Name _____

Translator Signature _____ **Date** _____

Witness

I observed the entire consent process and attest that the information in the English version of the consent document was presented to the 'Participant' listed above, in the following language, _____, any questions were answered and the 'Participant' appeared to understand the information.

Witness Printed Name _____

Witness Signature _____ **Date** _____

Legally Authorized Representative Name (only if applicable)

Your signature below means that you are the legally authorized representative for the 'Participant' named above; and that the research study, including the above information, has been described to you orally, your questions have been answered, and that you voluntarily give consent for his/her participation in this research study.

Printed Name _____

Signature _____ **Date** _____