

SHORT FORM CONSENT TO PARTICIPATE IN RESEARCH
For studies conducted in compliance with the revised Common Rule

PROTOCOL NO.:

SPONSOR:

INVESTIGATOR:

24 HR. TELEPHONE #:

The use of “you” throughout this document refers to the research subject. It also refers to the person authorized to give consent for the subject’s participation in this research study.

Consent to Participate in a Research Study

You are being asked to participate in a research study. Please take your time to make your decision and discuss it with your family and friends.

Before you agree to participate, the investigator must tell you:

- 1) The key information about this study, which must be presented first, before any other information is provided;
- 2) The purposes, procedures, and duration of the research;
- 3) Any procedures which are experimental;
- 4) Any reasonably foreseeable risks, discomforts, and benefits of the research;
- 5) Any potentially beneficial alternative procedures or treatments;
- 6) How confidentiality will be maintained and how your health information will be protected; and
- 7) Whether your deidentified (removal of details that make it possible to identify you) private information or biospecimens (for example, urine, blood, tissue) collected for this study could be used for future research studies without additional informed consent.

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) When you will be told about new findings that may affect your willingness to participate;
- 7) How many people will be in the study;
- 8) Whether your biospecimens (even if deidentified) may be used for commercial profit and whether you will share in this profit;
- 9) Whether you will be given clinically relevant research results, including individual research results, and if so, under what conditions;

- 10) Whether the research will (if known) or might include whole genome sequencing; and
- 11) For clinical trials: A description of this clinical trial will be available at www.ClinicalTrials.gov, as required by U.S. Law. The 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 will be given a signed and dated copy of this document and a copy of the English language consent form for the study.

You may contact the investigator at the telephone number listed on the first page of this form at any time if you have questions about the study or a research-related injury.

You may also contact Advarra's IRB. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
Study Subject Adviser
Advarra
6100 Merriweather Drive, Suite 600
Columbia, MD 21044
- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

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

Signing and dating this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate:

Documentation of Consent:

The person doing this research study has explained what will happen to me if I participate in this research study. My signature below means that I want to be in this research study. I can decide not to participate in this research study if I do not want to and nothing will happen to me if I decide I do not want to participate.

Subject's Printed Name

Subject's Signature (if subject is over the age of majority) _____
Date

Documentation of Assent (if applicable – if subject is under the age of majority)

Signature of Subject

Date

Legally Authorized Representative (as applicable):

Printed Name of Legally Authorized Representative

Signature of Legally Authorized Representative

Date

Authority of Legally Authorized Representative to act on behalf of Subject

Required:

Signature of Interpreter/Witness

Date

ADDENDUM FOR OPTIONAL STUDIES (IF APPLICABLE)

You are being asked to participate in some optional studies. If you decide not to participate in any of the optional studies, you can still participate in the main research study. Please take your time to make your decision and discuss it with your family and friends.

Your participation in these optional research studies is voluntary, and you will not be penalized or lose any benefits if you refuse to participate or decide to stop.

Please indicate whether or not you want to take part in the optional research studies.

Optional Study #1: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

Optional Study #2: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

Optional Study #3: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

Optional Study #4: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

Optional Study #5: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

Optional Study #6: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

Optional Study #7: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

Optional Study #8: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

Optional Study #9: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____

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Optional Study #10: _____

- Not applicable
- Yes Initials _____ Date _____
- No Initials _____ Date _____