

## TEMPLATE

*Every attempt should be made to use an understandable reading level in all consent documents. Subject/LAR should initial each page of the informed consent as it is explained to them.*

### SHORT FORM SUBJECT INFORMATION AND CONSENT FORM

Name of Research Study: \_\_\_\_\_

Protocol #: \_\_\_\_\_

Sponsor: \_\_\_\_\_

Principal Investigator Name: \_\_\_\_\_

Research Site Address (es): \_\_\_\_\_  
\_\_\_\_\_

Daytime telephone number(s): \_\_\_\_\_

24-hour contact number(s): \_\_\_\_\_

*In this consent form, the use of "you/yours" refers to the subject of the study, in cases where a Legally Authorized Representative (LAR) is being asked to consent on behalf of the subject.*

### INTRODUCTION

You are being asked to participate in a research study of \_\_\_\_\_.

Before you agree, the investigator must have told 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.

The investigator must also have told you about (i) any available compensation and medical treatment if injury occurs, and how to obtain them; (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.

The oral explanation includes all of the elements of informed consent as required by the U.S. Food and Drug Administration (FDA).

Subject's/LAR Initials \_\_\_\_\_

A description of this clinical trial will be available on <http://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 that was explained to you orally by the study doctor.

If you experience a side effect or injury that may be related to this study, if you have questions about this study, or if you have an unscheduled visit for medical care for any reason, please contact:

**Principal Investigator Name:** \_\_\_\_\_

**Daytime telephone number(s):** \_\_\_\_\_

**24-hour contact number(s):** \_\_\_\_\_

If you have questions about your rights as a research subject, you may contact Copernicus Group Independent Review Board (IRB) at 1-888-303-2224 (toll free). An IRB is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's safety and welfare in mind. Copernicus Group IRB has reviewed and approved the research study described in this Subject Information and Consent Form. If you have study-related comments, complaints or concerns, you should first contact the study investigator. Please call the IRB if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator. For further information regarding the clinical trials process and your role as a research subject, you may visit the Copernicus Group IRB website at [www.cgirb.com](http://www.cgirb.com).

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.

#### **AUTHORIZATION TO USE AND SHARE IDENTIFIABLE HEALTH INFORMATION**

If you sign this consent form, the study doctor will use your medical and research records at this facility. The study doctor may share identifiable information with the sponsor and its agents. The study doctor and sponsor may also share your information with:

- The FDA
- Department of Health and Human Services (DHHS)
- Governmental agencies in other countries
- Copernicus Group Independent Review Board (IRB)

This information is shared so the research can be conducted and properly monitored. Further information on how your personal health information may be used has been read to you

Subject's/LAR Initials\_\_\_\_\_

This permission will not end unless you cancel it. You may cancel it by sending written notice to the study doctor. If you cancel this permission, no other information will be collected, but information already obtained may still be used if needed for the study.

If you sign this consent form, your information may be released to the parties listed above, and then it may no longer be protected and they may release it to others without your permission.

If you do not sign this consent form, you cannot be in this research, but you will still be treated, and you will not lose any benefits to which you are otherwise entitled.

### **SUBJECT'S STATEMENT OF CONSENT**

*Study Title Here*

Signing this document means that the research study has been described to you orally. You voluntarily agree to participate in this experimental study.

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<b>Subject (Print Name)</b>	<b>Signature</b>	<b>Date</b>
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I certify that I have the legal authority under applicable law to make this request on behalf of the subject identified above:

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<b>Parent/Guardian or Legally Authorized Representative (Print Name)</b>	<b>Signature</b>	<b>Date</b>
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**Relationship to Subject (i.e. parent, guardian, legally authorized representative, power of attorney)**

### **IMPARTIAL WITNESS STATEMENT**

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently accepted by, the subject, or his/her Legally Authorized Representative. The subject or his/her Legally Authorized Representative freely consented to participate in the research study.

Subject's/LAR Initials \_\_\_\_\_

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**Impartial Witness's Name  
(Print Name)**

**Signature**

**Date**