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Applicable Regulation

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General

<input type="checkbox"/> The consent form provides the information in a language that is understandable to the subject or the subject's Legally Authorized Representative (LAR).			
<input type="checkbox"/> The information being communicated to the subject or the LAR during the consent process does not include exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights.			
<input type="checkbox"/> The information being communicated to the subject or the LAR during the consent process does not include exculpatory language through which the subject or the LAR releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.			
<input type="checkbox"/> The investigator will give either the subject/LAR adequate opportunity to read the consent document before it is signed			
<input type="checkbox"/> Simple explanation of the informed consent process.			

Reason for the Study

<input type="checkbox"/> Statement that the study involves research.	(a)	(a)(1)	(a)(1)
<input type="checkbox"/> General purpose(s) of the study.	(b)	(a)(1)	(a)(1)

General Information about the Study

<input type="checkbox"/> Description of the study methods, procedures, products or drugs.	(d)	(a)(1)	(a)(1)
<input type="checkbox"/> The study treatment(s) and the probability for (random) assignment to each treatment.	(c)	---	---
<input type="checkbox"/> The subjects' responsibilities.	(e)	---	---

Subject's Part in the Study

<input type="checkbox"/> Expected duration of the subject's participation and frequency of visits to the study site	(s)	(a)(1)	(a)(1)
<input type="checkbox"/> Approximate number of subjects involved in the study.	(t)	(b)(6)	(b)(6)
<input type="checkbox"/> Procedures to be followed and identification of those that are experimental.	(f) (d)	(a)(1)	(a)(1)

Possible Risks and Benefits

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<input type="checkbox"/> All reasonably foreseeable risks and discomforts to the subjects. Whenever possible, likelihood, severity, and duration of risks.	(g)	(a)(2)	(a)(2)
<input type="checkbox"/> <i>When appropriate: statement that the particular treatment or procedure may involve risks to the subjects (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.</i>	---	(b)(1)	(b)(1)
<input type="checkbox"/> Benefits to subjects or to others which may reasonably be expected from the research.	(h)	(a)(3)	(a)(3)
<input type="checkbox"/> <i>When appropriate: Significant new findings developed during research relating to subjects' willingness to continue participation will be provided to the subjects.</i>	(p)	(b)(5)	(b)(5)
If Subject Decides Not to Be in the Study			
<input type="checkbox"/> Participation is voluntary	---	(a)(8)	(a)(8)
<input type="checkbox"/> A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subjects. Where appropriate their important potential benefits and risks.	(i)	(a)(4)	(a)(4)
<input type="checkbox"/> Refusal to participate or to discontinue participation, at any time is without penalty or loss of benefits to which subjects are otherwise entitled.	(m)	(a)(8)	(a)(8)
Confidentiality			
<input type="checkbox"/> Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that the FDA, IRB, sponsor, and representatives of the sponsor will have direct access to the subjects' records, including the original medical record, to verify the study procedures and research data.	(n) representatives, monitors, auditors	(a)(5)	(a)(5)
<input type="checkbox"/> By signing a written informed consent form, the subject or the subject's LAR is authorizing such access.	(n)	---	---
<input type="checkbox"/> If the results of the study are published, subjects' identity will remain confidential.	(o)	---	---
<input type="checkbox"/> <i>For applicable clinical trials (see: Statements that a description of the clinical trial will be available on www.clinicaltrials.gov as required by U.S. Law, with no identifying information, at most with summary of results and able to be searched at any time.</i>		(c)	
<input type="checkbox"/> <i>When applicable: Genetic Information Nondiscrimination Act language included.</i>	---	---	---



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Compensation

<input type="checkbox"/> Any additional costs, to subjects that may result from participation in the study,	(l)	(b)(3)	(b)(3)
<input type="checkbox"/> <i>When applicable: statement about any monetary or other inducements for participation and how these will be prorated for subjects who do not complete the study.</i>	(k)		
<input type="checkbox"/> For research involving more than minimal risk, an explanation as to whether any <u>compensation</u> and an explanation as to whether any <u>medical treatments</u> are available if injury occurs. If so, what they consist of, or where further information may be obtained.	(j)	(a)(6)	(a)(6)

Leaving the Study

<input type="checkbox"/> <i>When applicable: circumstances and/or reasons under which subjects' participation may be terminated with or without their consent.</i>	(r)	(b)(2)	(b)(2)
<input type="checkbox"/> <i>When applicable: consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.</i>	---	(b)(4)	(b)(4)

Contact for Questions

<input type="checkbox"/> If subjects have questions or concerns about participation in the study or if they have a complaint about the research study, contact [Investigator 24-hour number].	(q)	(a)(7)	(a)(7)
<input type="checkbox"/> If subjects have questions about their rights while they are in the study, contact Copernicus Group IRB at 1-888-303-2224.	(q)	(a)(7)	(a)(7)
<input type="checkbox"/> Statement that the study has been approved by CGIRB	---	---	---



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Subpart D – Additional Safeguards for Children

<input type="checkbox"/> Will minor subjects be enrolled in the research?	---	---	---
<input type="checkbox"/> Are adequate provisions made for soliciting the assent of the children and the permission of their parents/guardians?	---	---	---

Long Form of Consent Documentation

<input type="checkbox"/> The consent document embodies the basic and appropriate additional elements of disclosure	---	50.(b)(1)	46.117(b)(1)
<input type="checkbox"/> The subject or the subject's LAR will sign (and date for FDA-regulated research), the consent document.		50.27(a)	R 46.117(a)
<input type="checkbox"/> The person who conducted the informed consent discussion will sign and date the consent document	4.8.8		
<input type="checkbox"/> A copy of the consent document will be given to the person signing the consent document		50.27(a)	46.117(a)
<input type="checkbox"/> The investigator will give either the subject or the subject's LAR adequate opportunity to read the consent document before it is signed.		50.27(b)(1)	46.117(b)(1)
<input type="checkbox"/> <i>When applicable:</i> An impartial witness will be present during the informed consent discussion and will sign and date the consent form attesting that the subject and/or the LAR have had the consent form and any written information about the study explained to them and that the subject or LAR has apparently understood this information. Informed consent was freely given by the subject or the subject's LAR.	4.8.9		

Potential subjects must be given all information that might reasonably be expected to influence their willingness to participate. This information should be provided in language understandable to the subject or the representative preferably at an 8th grade reading level. Additionally, the document should be free of any language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, the institution, or its agents from liability for negligence.

(When complete, electronic signature will be attached.)

Experienced Reviewer Signature

Date