



Subject Information and Consent Form Checklist

Internal Use

IRB Tracking #: _____

Applicable Regulation

ICH E6 4.8

21 CFR
50.20/
50.25

45 CFR
46.116

General

The subject information and consent form provides the information in a language that is understandable to the subject or the subject's LAR.

The information being communicated to the subject or the representative during the consent process does not include exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights.

The information being communicated to the subject or the legally authorized representative during the consent process does not include exculpatory language through which the subject or the legally authorized representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The investigator will give either the subject/LAR adequate opportunity to read the consent document before it is signed

Simple explanation of the informed consent process.

Reason for the Study

Statement that the study involves research.

(a)

(a)(1)

(a)(1)

General purpose of the study.

(b)

(a)(1)

(a)(1)

Appropriate, alternative procedures or courses of treatment that may be advantageous to the subject and their important potential benefits and risks.

(i)

(a)(4)

(a)(4)

General Information about the Study

Description of the study methods, procedures, products or drugs.

(d)

(a)(1)

(a)(1)

The study treatment(s) and the probability for random assignment to each treatment.

(c)

The subject's responsibilities.

(e)



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Subject's Part in the Study

<input type="checkbox"/> Expected duration of the subject's participation, frequency of trips to the study site, etc.	(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 when taking study drugs

<input type="checkbox"/> All reasonably foreseeable discomforts and risks to the subject. Whenever possible, likelihood, severity, and duration of risks.	(g)	(a)(2)	(a)(2)
<input type="checkbox"/> <i>When applicable: statement that the particular treatment or procedure may involve risks to the subject (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, that can reasonably be expected.	(h)	(a)(3)	(a)(3)
<input type="checkbox"/> Significant new findings developed during research will be provided to the subject.	(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"/> Subject is free to refuse to participate in the study at any time without penalty or loss of benefits to which you are otherwise entitled.	(m)	(a)(8)	(a)(8)

Confidentiality

<input type="checkbox"/> Statement that confidentiality will be maintained and that the FDA, IRB, sponsor, and representatives of the sponsor may have access to the subjects' records.	(n) representatives, monitors, auditors	(a)(5)	(a)(5)
<input type="checkbox"/> By signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.	(n)	---	---
<input type="checkbox"/> If the results of the study are published, the subject's identity will remain confidential.	(o)	---	---



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Compensation

<input type="checkbox"/> Costs to the subject that may result from participation in the study, if there are any.	(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)	(a)(6)	(a)(6)
<input type="checkbox"/> Explanation and description of any compensation and medical treatment available if injury occurs.	(j)	(a)(6)	(a)(6)

Leaving the Study

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

Contact for Questions



<input type="checkbox"/> If subjects have further questions about the study or if they have research related problems or injury, 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	---	---	---

If Subject Has a Problem

<input type="checkbox"/> If such a problem should occur and they need more help, what will happen and who is responsible for payment? (Compensation for research related injury clause)	(j)	(a)(7)	(a)(7)
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Signature Page

<input type="checkbox"/> Subject/LAR will sign and date the consent document	4.8.8	50.27	45CFR 46.117(a)
<input type="checkbox"/> Person obtaining consent will sign and date the consent document.	4.88	---	---
<input type="checkbox"/> The subject/LAR will receive a copy of the consent document	---	---	---

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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?	---	---	---

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.

Primary Reviewer Signature
Date