

**Required Elements for Informed Consent:**

Check Box	Required Element	FDA Studies	DHHS Studies	ICH Studies
<input type="checkbox"/>	A statement that the study involves <b>research</b>	21 CFR 50.25(a)(1)	45 CFR 46.116 (a)(1)	ICH E6 4.8.10 (a)
<input type="checkbox"/>	An explanation of the purposes of the research  (ICH adds -the trial treatment(s) and the probability for random assignment to each treatment)	21 CFR 50.25(a)(1)	45 CFR 46.116 (a)(1)	ICH E6 4.8.10 (b)  (c)
<input type="checkbox"/>	The expected duration of the subject's participation	21 CFR 50.25(a)(1)	45 CFR 46.116 (a)(1)	ICH E6 4.8.10 (s)
<input type="checkbox"/>	A description of the procedures to be followed  (ICH adds, including all invasive procedures)	21 CFR 50.25(a)(1)	45 CFR 46.116 (a)(1)	ICH E6 4.8.10 (d)
<input type="checkbox"/>	The subject's responsibilities	-----	-----	ICH E6 4.8.10 (e)
<input type="checkbox"/>	Identification of any procedures that are experimental	21 CFR 50.25(a)(1)	45 CFR 46.116 (a)(1)	ICH E6 4.8.10 (f)
<input type="checkbox"/>	A description of any reasonably foreseeable risks or discomforts to the subject.	21 CFR 50.25(a)(2)	45 CFR 46.116 (a)(2)	ICH E6 4.8.10 (g)
<input type="checkbox"/>	A description of any benefits to the subject or to others which might be expected from the research	21 CFR 50.25(a)(3)	45 CFR 46.116 (a)(3)	ICH E6 4.8.10 (h)
<input type="checkbox"/>	A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject.  ICH adds (alternative procedures and their risks and benefits)	21 CFR 50.25(a)(4)	45 CFR 46.116 (a)(4)	ICH E6 4.8.10 (i)
<input type="checkbox"/>	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and	21 CFR 50.25(a)(5)	45 CFR 46.116 (a)(5)	ICH E6 4.8.10 (o)
<input type="checkbox"/>	A statement that notes that the FDA may inspect the records.	21 CFR 50.25(a)(5)	-----	-----
<input type="checkbox"/>	A statement that a description of the clinical trial will be available on <a href="http://www.ClinicalTrials.gov">http://www.ClinicalTrials.gov</a> .	21 CFR 50.27 (c)	-----	-----

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<input type="checkbox"/>	That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority (ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that by signing the informed consent form, the subject or the subject's legally authorized representative is authorizing such access.	-----	-----	ICH E6 4.8.10 (n)
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	For research involving more than minimal risk, (1) an explanation as to whether any compensation and (2) an explanation as to whether any medical treatments will be available if injury occurs and, if so, what they consist of, and (3) where further information may be obtained .	21 CFR 50.25(a)(6)	45 CFR 46.116 (a)(6)	ICH E6 4.8.10 (j)
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	An explanation of whom to contact for answers to pertinent questions: (1) about the research (PI name and number) (2) and research subject's rights, discuss problems, concerns and questions; obtain information and offer input (IRB contact info [person unaffiliated with the research study]); and, (3) who to contact in the event of a research-related injury to the subject.	21 CFR 50.25(a)(7)	45 CFR 46.116 (a)(7)	ICH E6 4.8.10 (q)
<input type="checkbox"/> <input type="checkbox"/>	A statement that participation is voluntary A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.	21 CFR 50.25(a)(7)	45 CFR 46.116 (a)(8)	ICH E6 4.8.10 (m)
<b>Additional Elements (Required when applicable)</b>				
<input type="checkbox"/>	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or becomes pregnant) which are currently unforeseeable.	21 CFR 50.25(b)(1)	45 CFR 46.116 (b)(1)	ICH E6 4.8.10 (g)
<input type="checkbox"/>	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	21 CFR 50.25(b)(2)	45 CFR 46.116 (b)(2)	ICH E6 4.8.10 (r)
<input type="checkbox"/>	Additional costs to the subject that may result from participation in the study.	21 CFR 50.25(b)(3)	45 CFR 46.116 (b)(3)	ICH E6 4.8.10 (l)

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<input type="checkbox"/>	Compensation or payment to subjects for participating in the trial & the schedule of the payments	-----	-----	ICH E6 4.8.10 (k)
<input type="checkbox"/>	The consequences of a subject's decision to withdraw from the course of the research, <u>and</u>	21 CFR 50.25(b)(4)	45 CFR 46.116 (b)(4)	-----
<input type="checkbox"/>	Procedures for the orderly termination of participation by the subject.			
<input type="checkbox"/>	A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.	21 CFR 50.25(b)(5)	45 CFR 46.116 (b)(5)	ICH E6 4.8.2 ICH E6 4.8.10 (p)
<input type="checkbox"/>	The approximate number of subjects in the study.	21 CFR 50.25(b)(6)	45 CFR 46.116 (b)(6)	ICH E6 4.8.10 (t)
<input type="checkbox"/>	Date of the subject's (or legally authorized representative's) signature.	21 CFR 50.27(a)	45 CFR 46.117(a)	ICH E6 4.8.8
<input type="checkbox"/>	A copy of the signed written ICF will be provided to the subject.  ICH "signed and dated"	21 CFR 50.27(b)	45 CFR 46.117(a)	ICH E6 4.8.11
<input type="checkbox"/>	Signature of the subject or legally authorized representative	21 CFR 50.27(a)	45 CFR 46.117(a)	ICH E6 4.8.8
<input type="checkbox"/>	Signature of the person obtaining consent	-----	-----	ICH E6 4.8.8
<input type="checkbox"/>	Signature of witness  ICH "impartial" witness	21 CFR 50.27(b)(2) – short form	45 CFR 46.117(b)(2) – short form	ICH E6 4.8.9
<b>State, Site or IRB Specific Requirements</b>				
<input type="checkbox"/>	California Patient Bill of Rights (separate front page with signature /date line for subject or Legally Authorized Representative)			
<input type="checkbox"/>	Statement that a copy of the signed written ICF will be provided to the subject			
<input type="checkbox"/>	Date of the subject's (or legally authorized representative's) signature.			
<input type="checkbox"/>	Printed name & signature of the subject or legally authorized representative			
<input type="checkbox"/>	Date of the person explaining and witnessing consent's signature.			
<input type="checkbox"/>	Printed name & signature of the person explaining and witnessing consent			
<input type="checkbox"/>	Time of subject's (or legally authorized representative's) signature & time of signature of person explaining & witnessing the consent			