INFORMED CONSENT CHECKLIST

Generally, the Sponsor or Clinical Research Organization will provide a templated consent form. The person doing regulatory submissions for the study will have to insert their site's and /or IRB standard language prior to submission to the IRB. Clinical Research Personnel or Monitors may use this ICF checklist to ensure that all required elements of the informed consent are met when reviewing site ICFs prior to IRB submission. Note: depending on the protocol or sponsor, more than one set of regulations/guidelines may apply.

ICH Guideline requirements are not required per the U.S. regulations. Sponsors of international studies may follow ICH Guidelines and because of this, they are indicated here for reference.

Required Elements for Informed Consent:

Check Box	Required Element	FDA Studies	DHHS Studies	ICH Studies
☐	A statement that the study involves **research**	21 CFR 50.25(a)(1)	45 CFR 46.116 (a)(1)	ICH E6 4.8.10 (a)
☐	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)
☐	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)
☐	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)
☐	The subject's responsibilities	----------	----------	ICH E6 4.8.10 (e)
☐	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)
☐	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)
☐	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)
☐	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)
☐	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)
☐	A statement that notes that the FDA may inspect the records.	21 CFR 50.25(a)(5)	----------	----------

Check Box	Required Element	FDA Studies	DHHS Studies	ICH Studies
☐	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)
☐ ☐ ☐	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)
☐ ☐ ☐	An explanation of whom to contact for answers to pertinent questions: (1) about the research (PI name and number), and, (2) research subject's rights (IRB contact info), 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)
☐ ☐	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)
Additional Elements (Required when applicable)				
☐	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)
☐	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)
☐	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)
☐	Compensation or payment to subjects for participating in the trial.	----------	----------	ICH E6 4.8.10 (k)

Check Box	Required Element	FDA Studies	DHHS Studies	ICH Studies
☐ ☐	The consequences of a subject's decision to withdraw from the course of the research, and Procedures for the orderly termination of participation by the subject.	21 CFR 50.25(b)(4)	45 CFR 46.116 (b)(4)	----------
☐	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)
☐	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)
☐	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
☐	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
☐	Signature of the subject or legally authorized representative	21 CFR 50.27(a)	45 CFR 46.117(a)	ICH E6 4.8.8
☐	Signature of the person obtaining consent	----------	----------	ICH E6 4.8.8
☐	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
STATE, SITE OR IRB SPECIFIC REQUIREMENTS				
☐	California Patient Bill of Rights (separate front page with signature /date line for subject or Legally Authorized Representative)			
☐	IRB Required Signatures: (such as) Signature of Investigator Signature of Witness Other:			