INFORMED CONSENT CHECKLIST

Required Elements of Informed Consent (per 45 CFR 46.116, 21 CFR 50.25, ICH GCP E6 Guideline 4.8.10)

Met	Not Met	NA	Element	Regulatory reference
			A statement that the study involves research,	45 CFR 46.116 (a) (1); 21 CFR 50.25 (a) (1); ICH E6 4.8.10 (a)
			An explanation of the purposes of the research,	45 CFR 46.116 (a) (1); 21 CFR 50.25 (a) (1); ICH E6 4.8.10 (b)
			An explanation of the expected duration of subject's participation,	45 CFR 46.116 (a) (1); 21 CFR 50.25 (a)(1); ICH E6 4.8.10 (s)
			A description of the procedures to be followed,	45 CFR 46.116 (a) (1); 21 CFR 50.25 (a) (1) ; ICH E6 4.8.10 (d)
			Identification of any procedures which are experimental;	45 CFR 46.116 (a) (1); 21 CFR 50.25 (a) (1); ICH E6 4.8.10 (f)
			A description of the treatment(s) and the probability for random assignment to each treatment.	ICH E6 4.8.10 (c)
			A description of any reasonably foreseeable risks or discomforts to the subject;	45 CFR 46.116 (a) (2); 21 CFR 50.25 (a) (2); ICH E6 4.8.10 (g)
			A description of any benefits to the subject or to others which may reasonably be expected from the research;	45 CFR 46.116 (a) (3); 21 CFR 50.25 (a) (3); ICH E6 4.8.10 (h)
			A disclosure of appropriate alternative procedures or courses of treatments, if any, that may be advantageous to the subject;	45 CFR 46.116 (a) (4); 21 CFR 50.25 (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,	45 CFR 46.116 (a) (5); 21 CFR 50.25 (a) (5); ICH E6 4.8.10 (o)
			Language to indicate the extent permitted by the applicable laws and/or regulations, will not be made publicly available and that if the results of the trial are published, the subject's identity will remain confidential.	ICH E6 4.8.10 (o)
			A statement that the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) *(including FDA for FDA regulated studies)* 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 a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.	21 CFR 50.25 (a) (5); ICH E6 4.8.10 (n)
			For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs, an explanation as to whether any medical treatments are available if injury occurs, and if so, what they consist of, OR where further information may be obtained;	45 CFR 46.116 (a) (6); 21 CFR 50.25 (a) (6); ICH E6 4.8.10 (j)
			An explanation of whom to contact for answers to pertinent questions about the research and	45 CFR 46.116 (a) (7); 21 CFR 50.25 (a) (7); ICH, E6 4.8.10 (q)

Met	Not Met	NA	Element	Regulatory reference
			An explanation of whom to contact in the event of a research-related injury to the subject;	45 CFR 46.116 (a) (7); 21 CFR 50.25 (a) (7); ICH, E6 4.8.10 (q)
			A statement that participation is voluntary,	45 CFR 46.116 (a) (8); 21 CFR 50.25 (a) (8); ICH E6 4.8.10 (m)
			A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; a statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.	45 CFR 46.116 (a) (8); 21 CFR 50.25 (a) (8); ICH E6 4.8.10 (m)
			A description of the subject's responsibilities	ICH E6 4.8.10 (e)
			One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.	45 CFR 46.116 (a) (9)

Additional Elements of Informed Consent, required as applicable Consent (per 45 CFR 46.116, 21 CFR 50.25, ICH Guideline 4.8.10)

Met	Not Met	NA	Element	Regulatory reference
			A statement that the particular treatment or procedure may involve risks to the subject (or embryo, or fetus, or nursing infant if subject is or may become pregnant) which are currently unforeseeable;	45 CFR 46.116 (b) (1); 21 CFR 50.25 (b) (1); ICH E6 4.8.10 (g)
			Anticipated circumstances under which a subject's participation may be terminated by the investigator without regard to the subject's consent;	45 CFR 46.116 (b) (2); 21 CFR 50.25 (b) (2); ICH E6 4.8.10 (r)
			Any additional costs to the subject that may result from participation in the research;	45 CFR 46.116 (b) (3); 21 CFR 50.25 (b) (3); ICH E6 4.8.10 (l)
			A statement describing the anticipated prorated payment, if any, to the subject for participating in the trial.	ICH E6 4.8.10 (k)
			The consequences of a subject's decision to withdraw from the research and	45 CFR 46.116 (b) (4); 21 CFR 50.25 (b) (4)
			A description of the procedures for orderly termination of participation by the subject;	45 CFR 46.116 (b) (4); 21 CFR 50.25 (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 or the subject's legally acceptable representative in a timely manner;	45 CFR 46.116 (b) (5); 21 CFR 50.25 (b) (5); ICH E6 4.8.10 (p)
			Approximate number of subjects involved in the study.	45 CFR 46.116 (b) (6); 21 CFR 50.25 (b) (6); ICH E6 4.8.10 (t)
			A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.	45 CFR 46.116 (b) (7)
			A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.	45 CFR 46.116 (b) (8)
			For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).	45 CFR 46.116 (b) (9)
			Language to include if your study will be posted on Clinicaltrials.gov: "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."	