Informed Consent Elements Checklist

Complete	GCP References	Elements
	46.116(a)(5)(ii)	A concise summary of the study as a whole that precedes all other elements of consent
	46.116(a)(5)(ii)	That participation is voluntary and a participant may leave the study at any time without penalty
	21CFR 50.25a1 **45 CFR** **46.116a ICH**	That the trial involves research.
	21CFR 50.25a1 **45 CFR** **46.116a1 ICH**	The purpose of the trial.
	ICH GCP 4.8.10 c	The trial treatment(s) and the probability for random assignment to each treatment.
	21CFR 50.25 a1 **45 CFR** **46.116a1 ICH**	The trial procedures to be followed, including all invasive procedures
	ICH GCP 4.8.10 e	The subject's responsibilities.
	21CFR 50.25 a1 **45 CFR** **46.116a1 ICH**	Those aspects of the trial that are experimental.
	21CFR 50.25a2 **45 CFR 46.116a2, b1** **ICH GCP 4.8.10 g**	The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
	21CFR 50.25a3 **45 CFR** **46.116a3 ICH**	The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

	21CFR 50.25 a4 **45 CFR** **46.116a4 ICH**	The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.
	21CFR 50.25 a6 **45 CFR** **46.116a6 ICH**	The compensation and/or treatment available to the subject in the event of trial-related injury.
	ICH GCP 4.8.10 k	The anticipated prorated payment, if any, to the subject for participating in the trial.

Complete	GCP References	Element
	21CFR 50.25 b3 **45 CFR** **46.116b3 ICH**	The anticipated expenses, if any, to the subject for participating in the trial.
	21CFR 50.25a8, b4 **45 CFR 46.116 a8, b4** **ICH GCP 4.8.10 m**	That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
	21CFR 50.25 a5 **45 CFR** **46.116a5 ICH** **GCP 4.8.10 n**	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 a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.
	21CFR 50.25 a5 **45 CFR** **46.116a5 ICH**	That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
	21CFR 50.25 b5 **45 CFR 46.116 b5** **ICH GCP 4.8.10 p**	That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
	21CFR 50.25 a7 **45 CFR 46.116 a7** **ICH GCP 4.8.10 q**	The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
	21CFR 50.25 b2 **45 CFR 46.116 b2** **ICH GCP 4.8.10 r**	The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
	21CFR 50.25 a1 **45 CFR** **46.116a1 ICH**	The expected duration of the subject's participation in the trial.
	21CFR 50.25 b6 **45 CFR** **46.116b6 ICH**	The approximate number of subjects involved in the trial.
	21 CFR 50.25(c)	The subject is informed that studies applicable as defined by 42 U.S.C. 282(j)(1)(A) will be submitted for inclusion in the clinical trial registry databank using the statement, "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website 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." See next page for more info

42 U.S.C. 282(j)(1)(A)

j)EXPANDED CLINICAL TRIAL REGISTRY DATA BANK
(1)DEFINITIONS; REQUIREMENT
(A)Definitions In this subsection:

(i)Applicable clinical trial
The term "applicable clinical trial" means an applicable device clinical trial or an applicable drug clinical trial.

(ii)Applicable device clinical trial The term "applicable device clinical trial" means—

(I)
a prospective clinical study of health outcomes comparing an intervention with a device subject to section 360(k), 360e, or 360j(m) of title 21against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

(II)
a pediatric postmarket surveillance as required under section 360/ of title 21.

(iii)Applicable drug clinical trial

(I)In general
The term "applicable drug clinical trial" means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 355 of title 21 or to section 262 of this title.