Informed Consent Form Checklist

Job-Aid for ensuring an informed consent form complies with Good Clinical Practice Guidelines E6 §4.8

	Statement that the study involves research
	Explanation of the purposes of the research
	Expected number of trial subjects to be enrolled
	The expected duration of the subject's participation
	Explanation of the subject's responsibilities
	Identification of trial procedures to be followed, including all invasive procedures
	Identification of any procedures that are experimental
	Explanation of the trial treatments and the probability for random assignment to each treatment
	Description of any reasonably foreseeable risks or discomforts to the subject
	Description of any reasonably expected benefits to the subject or to others
	Details on any anticipated prorated payments to the subject for participating in the trial
	Details on any anticipated expenses to the subject for participating in the trial
	Disclosure of appropriate alternative procedures or courses of treatment
	Statement describing the extent to which confidentiality of records identifying the subject will be maintained
	A statement indicating that regulatory authorities, monitors, auditors and ethics boards may inspect the subject's records
	An explanation as to whether any compensation is available if injury occurs, and a description of what they consist of
	Whom to contact for further information
	Whom to contact for answers to pertinent questions about the research
	Whom to contact for answers to pertinent questions about the research subject's rights
	Whom to contact in the event of a research related injury
	Statement that participation is voluntary
	Statement that refusal to participate will involve no penalty or loss of benefits
	Statement that subject may discontinue participation at any time without penalty or loss of benefits
	Statement that significant new findings uncovered during the course of the research will be provided to the subject