

Informed Consent Checklist

DHHS Office of Human Research Protections 45 §46.116 and 21 §50.25 Food and Drug Administration (FDA)

Studies that use an informed consent template other than those provided by their IRB (or CIRB) must add the IRB required header/footer (<http://www.med.umich.edu/irbmed/ict/eResearch-IC-Other-Header.doc>). Also, footnote/comment where in a proposed documents each of the elements is being met. This assures all elements are included and speeds the review process.

Basic and Additional Elements (required if appropriate to the study)

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to the subject or to others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. For studies under FDA oversight it must also note the possibility that the Food and Drug Administration may inspect the records.
	For research involving more than minimal risk, an explanation as to whether any compensation, and 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
	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
Additional elements, as appropriate	
	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 may become pregnant), which are currently unforeseeable
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	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
	The approximate number of subjects involved in the study

If the study falls under the FDA's oversight the consent must be dated when signed.

If neonates, children, children who are wards of the state, pregnant women, or fetuses are to be enrolled in the study additional regulations apply. For studies involving children as subjects the IRB is required to determine if assent of the subjects must be obtained in addition to parent's permission before research can proceed.