Consent Requirements

r	CFR Consent Form Required Elements:
	Process must maximize communication and minimize coercion or undue influence (e.g., appropriate incentives, clear list of consent items when appropriate). [32 CFR 219.116]
	The language must be understandable to the subject. [32 CFR 219.116]
	May not include exculpatory language in which subject waives (or appears to waive) legal rights. [32 CFR 219.116]
	Statement that the project involves research; the purpose of the research; a statement of duration of the participation; description of the procedures; and description of which procedures are experimental. [32 CFR 219.116(a)(1)]
	Description of reasonable foreseeable risks or discomforts. [32 CFR 219.116(a)(2)]
	Description of any benefits. [32 CFR 219.116(a)(3)]
	Disclosure of alternative procedures (when applicable). [32 CFR 219.116(a)(4)]
	Description of extent to which confidentiality of records will be maintained. [32 CFR 219.116(a)(5)]
	For more than minimal risk, statement describing compensation and/or medical treatments available if injury occurs. [32 CFR 219.116(a)(6)]
	Contact information: general study information and express concerns. [32 CFR 219.116(a)(7)]
	Statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. Subject may discontinue participation at any time. [32 CFR 219.116(a)(8)]
	Additional Requirements:
	Limitations on confidentiality; duty to report; etc.
	Vocabulary level must be appropriate for the audience. [32 CFR 219.116]

r	CFR Additional Consent Form Elements (When Appropriate):
	Statement that the treatment or procedure may involve risks to the subject. [32 CFR 219.116(b)(1)]
	Circumstances under which participation may be terminated by the investigator. [32 CFR 219.116(b)(2)]
	Any additional costs to the subject that may result from participation in the research. [32 CFR 219.116(b)(3)]
	Consequences of withdrawal from the research and procedures for orderly withdrawal. [32 CFR 219.116(b)(4)]
	Statement that significant new findings will be provided to the subject. [32 CFR 219.116(b)(5)]
	Approximate number of subjects involved in the study. [32 CFR 219.116(b)(6)]

r	The IRB may approve a consent procedure which alters or waives some or all of the elements of informed consent if it finds and documents that:
	The research involves no more than minimal risk to the subjects; [32 CFR 219.116(d)(1)]
	The waiver or alteration will not adversely affect the rights and welfare of the subjects; [32 CFR 219.116(d)(2)]
	The research could not practicably be carried out without the waiver or alteration; [32 CFR 219.116(d)(3)]

Consent Requirements

	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. [32 CFR 219.116(d)(4)]

r	**Documentation of Informed Consent may be Waived if:**
	For greater than minimal risk research, the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. [32 CFR 219.117(c)(1)] OR
	The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. [32 CFR 219.117(c)(2)]

r	**10 USC 980. Limitation On Use Of Humans As Experimental Subjects***
	(a) Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless--
	(1) the informed consent of the subject is obtained in advance; or
	(2) in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance.
	(b) The Secretary of Defense may waive the prohibition in this section with respect to a specific research project to advance the development of a medical product necessary to the armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws.

*DoD Directive 3216.02 defines research involving a human being as an experimental subject as an activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose.

*10 USC 980 does not apply to exempt research.