

@ Items <u>required</u> by regulation [45 CFR 46.116(a)]		Yes	n/a	No
@ [(a)(1)]	A. A clear statement that the study is " <u>research</u> "	—	—	—
@ [(a)(1)]	B. <u>All the research purposes</u> [<i>i.e.</i>			
[(b)(6)]	C. How, why, & how many prospective volunteers are <u>selected</u>	—	—	—
@ [(a)(1)]	D. Expected <u>duration</u> of the volunteer's involvement	—	—	—
@ [(a)(1)]	E. <u>Procedure(s) or treatment(s)</u> to be done	—	—	—
@ [(a)(3)]	F. Reasonably expected <u>benefits</u> to volunteer and others	—	—	—
@ [(a)(2)]	G. Reasonably foreseeable <u>discomfort and risks</u>	—	—	—
[(b)(1)]	H. Especially for experiments, a statement that the treatment(s) or procedure(s) "may involve risks that are currently unforeseeable"	—	—	—
@ [(a)(1)]	I. Which procedure(s) or treatment(s) are <u>experimental</u>	—	—	—
@ [(a)(4)]	J. The <u>alternatives</u> to the research's diagnostic method or treatment	—	—	—
[(b)(4)]	K. Procedure for the <u>orderly termination</u> of a volunteer's participation	—	—	—
[(b)(4)]	1) Consequences of a volunteer's <u>withdrawal</u> from the research	—	—	—
[(b)(2)]	2) When may the researcher <u>terminate</u> a volunteer's participation without the volunteer's consent	—	—	—
[(b)(5)]	L. Plans to <u>inform</u> volunteers of <u>significant research findings</u> during or after the study relevant to their continued participation or treatment	—	—	—
@ [(a)(6)]	M. If > minimal risk: " <u>In case of injury or severe adverse affect...</u> "	—	—	—
@	1) will <u>medical care for adverse affects</u> be given? who? where?	—	—	—
@	2) is <u>compensation for adverse affects</u> available? how?	—	—	—
@ [(a)(6)&(7)]	3) <u>whom</u> should a volunteer contact with injury or adverse affect?	—	—	—
@ [(a)(7)]	N. Who will answer <u>questions about the research itself?</u>	—	—	—
@ [(a)(5)]	O. How <u>confidentiality</u> (—) or <u>anonymity</u> (—) are maintained	—	—	—
@ [(a)(7)]	P. Who on IRB will answer <u>complaints, grievances, or other concerns?</u>	—	—	—
[(b)(3)]	Q. <u>Financial</u> factors (<u>extra costs of</u> , or compensation for, participation)	—	—	—
[.109(b)]	R. <u>Other elements</u> a reasonable person would want to know	—	—	—

@ [(a)(8)]

S.

Non-coercion disclaimer. *E.G.*

may refuse to take part without any penalty or loss of care or services by IHS or others. You may stop taking part at any time, without penalty or loss of care or services to which you are otherwise entitled." — — —