Review of Required and Additional Elements

Verify that the informed consent document contains each of the eight required elements (45 CFR 46.116)

Yes	No	Item #	ITEMS
			8 REQUIRED ELEMENTS
		1a	a statement that the study involves research, and
		1b	an explanation of the purposes of the research, and
		1c	the expected duration of the participant ‘s participation, and
		1d	a description of the procedures to be followed, and
		1e	identification of any procedures which are experimental;
		2	a description of any reasonably foreseeable risks or discomforts to the participant;
		3	a description of any benefits to the participant or to others which may reasonably be expected from the research
		4	a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
		5a	a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and
		5b	if the research is subject to Food and Drug Administration (FDA) regulation, a statement that notes the possibility that FDA may inspect the records
		6a	for research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs, and
		6b	an explanation as to whether any medical treatments are available if injury occurs and,
		6c	if so, what they consist of, or where further information may be obtained;
		7a	an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and
		7b	whom to contact in the event of a research-related injury to the participant;
		8a	a statement that participation is voluntary, and
		8b	a statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and
		8c	a statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

When appropriate, which of the following additional elements of information are provided in the consent form?

Yes	NA	Item #	ITEMS
			7 ADDITIONAL ELEMENTS
		1a	a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable; and
		1b	if the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable;
		2	anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent;
		3	any additional costs to the participant that may result from participation in the research;
		4	if this is a clinical trial, a statement that the research will be entered into the clinical trials.gov website;
		5a	the consequences of a participant’s decision to withdraw from the research; and
		5b	procedures for orderly termination of participation by the participant;
		6	a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant
		7	the approximate number of participants involved in the study.