HHS Definition of Minimal risk *(46.102i): Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test.*		
Required Elements: (*elements can be omitted if there are none)		
	7.1	A statement that the study involves research.
	7.2	An explanation of the purposes of the research.
	7.3	An explanation of the expected duration of the subject's participation.
	7.4	A description of the procedures to be followed.
	7.5	Identification of any procedures, which are experimental.*
	7.6	A description of any reasonably foreseeable risks or discomforts to the subject.*
	7.7	A description of any benefits to the subject or to others, which may reasonably be expected from the research.*
	7.8	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
	7.9	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.*
	7.10	For FDA-regulated research, a statement that notes the possibility that the Food and Drug Administration may inspect the records.
	7.11	For research involving more than minimal risk an explanation as to whether any compensation is available if injury occurs and, if so, what it consist of, or where further information may be obtained.
	7.12	For research involving more than minimal risk 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.
	7.13	An explanation of how to contact the research team for questions, concerns, or complaints about the research.
	7.14	An explanation of how to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.
	7.15	An explanation of whom to contact in the event of a research-related injury to the subject.
	7.16	A statement that participation is voluntary.
	7.17	A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
	7.18	A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
Definition of a Clinical Trial: *A biomedical or behavioral research study of human subjects designed to answer specific questions about* ***therapeutic*** *interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new* ***therapeutic*** *interventions are safe, efficacious, and effective.*		
Additional Required Elements for Clinical Trials:		
	7.19	The approval/favorable opinion by the IRB.
	7.20	The probability for random assignment to each treatment.
	7.21	The subject's responsibilities
	7.22	When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
	7.23	The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
	7.24	When there is no intended clinical benefit to the subject, a statement to this effect.
	7.25	A statement that monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
	7.26	If the results of the trial are published, the subject's identity will remain confidential.
	7.27	The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
	7.28	The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.
Additional Elements to Include when Appropriate:		

	7.29	A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
	7.30	A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
	7.31	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
	7.32	Any additional costs to the subject that may result from participation in the research.
	7.33	The consequences of a subject's decision to withdraw from the research.
	7.34	Procedures for orderly termination of participation by the subject.
	7.35	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.
	7.36	The approximate number of subjects involved in the study.
	7.37	The amount and schedule of all payments.
	7.38	The mandatory statement regarding the clinical trials database (when FDA regulated).
Release of Protected Health Information (PHI) for Research Purposes:		
	8.1	An explanation of HIPAA and PHI
	8.2	A description of what will be done with the PHI
	8.3	A description of the why (purpose) the PHI is needed
	8.4	A description of what PHI will be released
	8.5	An description that lists who may have access to the PHI
	8.6	A statement of the duration of the authorization
	8.7	An explanation on how the patient can stop the information from being used
	8.8	A name and address of who the written notice to stop must be sent to
	8.9	A statement that authorization of use of PHI is required to participate in the study
	8.10	An indication of how long the PHI will be kept
Required Signature Lines:		
	9.1	Line for printed name of subject or child
	9.2	Signature line and date for subject or parent/legal guardian of child
	9.3	Line for printed name of person obtaining consent
	9.4	Signature line and date for person obtaining consent
Additional Signature Lines to Include when Appropriate:		
	9.5	If subjects will be illiterate or visually impaired, statement of what the impartial witness will witness
	9.6	If subjects will be illiterate or visually impaired, line for printed name of impartial witness
	9.7	If subjects will be illiterate or visually impaired, signature line and date for impartial witness
	9.8	If research is greater than minimal risk with no prospect of direct benefit for a minor, line for printed name of second parent/legal guardian of child
	9.9	If research is greater than minimal risk with no prospect of direct benefit for a minor, signature line and date for second parent/legal guardian of child
	9.10	If adult subjects will lack capacity to make an informed decision, line for printed name of Legally Authorized Representative (LAR)
	9.11	If adult subjects will lack capacity to make an informed decision, signature line and date for LAR
	9.12	If the child will be a ward of the state and the research is greater than minimal risk with no prospect of direct benefit, line for printed name of IRB assigned advocate
	9.13	If the child will be a ward of the state and the research is greater than minimal risk with no prospect of direct benefit, signature line and date for IRB assigned advocate
	9.14	If the study requires written assent of minors or adults who lack decision making capacity included in informed consent document, line for printed name of subject to assent
	9.15	If the study requires written assent of minors or adults who lack decision making capacity included in informed consent document, signature line and date for printed name of subject to assent in capable