1. Criterion #1: Minimization of Risks
	1. Risks to subjects are minimized?
		* Research procedures are consistent with sound research design
		* Research procedures do not unnecessarily expose subjects to risk
		* Researcher is qualified to conduct study
	2. If Applicable:
		* Routine or standard procedures to be performed on subjects for the purpose of the study whenever possible
2. Criterion #2: Risks-Benefit Relationship
	1. Risks to subjects are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may be expected to result
		* Purpose of study is clear and acceptable
		* Duration of the study is clear and appropriate
		* Number of subjects and duration of participation/follow-up is stated and appropriate
	2. If Applicable:
		* Results of any related studies are included
		* Compensation paid to subjects is appropriate?
		* Is there a control group? If yes, use of controls is appropriate and does not place any subjects at risk
3. Criterion #3: Equitable Selection
	1. Selection of subjects is equitable
		* Selection of subjects reflects purposes of the research and group(s) that will benefit from research outcome
		* Justification for use of vulnerable groups provided
		* Additional safeguards have been included in the study to protect the rights and welfare of these groups
4. Criteria #4-5: Consent Process and Documentation
	1. Legally effective informed consent is obtained
		* Informed Consent will be sought from each subject
		* Informed Consent procedures and documentation appear to be appropriate
		* Does the protocol call for waiver of any elements of informed consent? IF yes, is waiver appropriate, that is:
			+ The research involves no more than minimal risk to the subjects?
			+ The waiver of alteration will not adversely affect the rights and welfare of the subjects?
			+ Whenever appropriate, the subjects will be provided with additional pertinent information after participation?
				- Is a debriefing form provided?
5. Criterion #6: When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
	1. If appropriate, has a data and safety monitoring plan been submitted?
6. Criterion #7: Privacy/Confidentiality
	1. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data described in protocol?
7. Criterion #8: Standard Operating Procedures
	1. Are the required protocol elements present?
		* Statement of objects and purpose of the study?
		* Name, email address, and phone number of Investigator and statement of qualifications of each Investigator and Sub-investigator
		* Name of each facility where research will be performed by Investigator
		* Name of each facility where research will be performed by other, non-Institution/Organization employees
		* Name of each IRB to be used (if research sites above have IRBs)
		* Subject selection criteria, exclusion criteria and estimated number to be studies
		* Summary of study design, including control(s) and steps to reduce risk of bias
		* Observation and measurements to be made during the study described
		* Measures to be taken to monitor the research effects and minimize risks to subjects
		* Summary of data analysis and statistical methods to be used