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