PARTNERS HUMAN RESEARCH COMMITTEE
CRITERIA FOR IRB APPROVAL OF RESEARCH
45 CFR 46.111 and 21 CFR 56.111
POINTS TO CONSIDER

RISKS TO SUBJECTS ARE MINIMIZED

(a)(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- Have the rationale and basis for the study hypothesis been provided in the background information?
- Has the research been preceded by adequate laboratory and/or animal studies?
- Are the design of the research and the proposed research procedures adequate to answer the research questions posed?
- Can data from procedures or tests being performed for diagnostic or treatment purposes be used in lieu of procedures or tests being performed solely for research purposes?
- Could procedures that involve less risk be used to answer the research question?
- Is the sample size (number of subjects) adequate?
- Is the method proposed for selecting and assigning subjects to treatment groups unbiased?
- Are the study endpoints and methods of data analysis appropriate for the study?

RISK/BENEFIT RATIO

(a)(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

- What are the anticipated physical, psychological, social, legal, or economic risks to individual subjects?
- What are the potential benefits, if any, to individual subjects?
- What information is likely to result from the research and what impact, if any, will the information have on furthering the understanding of human physiology or diagnosis or treatment of the disease or condition being studied?
- Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? Are the procedures for identifying such individuals adequate?
- Are there adequate plans to exclude subjects who are vulnerable to injury during the period of withdrawal of active and effective therapy, if that is part of the research design?

EQUITABLE SELECTION OF SUBJECTS

(a)(3) Selection of subjects is equitable.

- Does the nature of the research require or justify using the proposed study population?
- Will the solicitation of subjects avoid placing a disproportionate share of the risks and discomfort as well as inconvenience of the research on any single group of individuals?
- Are women of childbearing potential eligible for participation or, if not eligible, has their exclusion been justified?
- Has the selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
- Are any payments to subjects reasonable, based upon the complexities and inconveniences of the study and the particular subject population?

INFORMED CONSENT PROCESS

(a)(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 and 21 CFR 50.25.

- Who will be explaining the research to potential subjects? Should the principal investigator or physician co-investigators be required to obtain consent? Should someone in addition to or other than the investigator be involved in the consent process (e.g., subject advocate)?
- Does the investigator serve a dual role that may pose a conflict of interest?
- Will the consent process take place under conditions most likely to provide potential subjects an opportunity to make a decision about participation without undue pressure?

DOCUMENTATION OF INFORMED CONSENT

(a)(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 and 21 CFR 50.27.

- Are the language and presentation of the information to be conveyed appropriate to the subject population, taking into consideration the reading level, use of complex sentence structure and use of technical terms as well as the need for translation into languages other than English?
- Do the consent documents describe the study design (including plans for randomization, use of placebos, and the probability that the subject will receive a given treatment) and conditions for breaking the code (if the study is masked)?
- Do the consent documents describe the risks and benefits of each of the proposed interventions and alternative courses of action available to the participants?
- Do the consent documents clearly describe the extent to which participation in the study precludes other therapeutic interventions?

DATA AND SAFETY MONITORING

(a)(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- How will the trial be monitored? Is the plan appropriate given the risks, size, type and complexity of the trial?
- How will decisions about stopping the trial be made? By whom? On what basis?

PRIVACY AND CONFIDENTIALITY PROTECTIONS

(a)(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- Do the methods for recruiting and consenting subjects adequately protect their privacy?
- Are study related discussions or interviews conducted in a private setting?
- If the investigator wants to review existing records to select subjects for further study, are subjects recruited through their physician or health care provider involved in their care?
- Will the investigator(s) be collecting sensitive information about individuals (e.g., related to sexual practices, substance abuse, or illegal behavior)? If so, have they made adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study?
- If the information obtained about subjects might interest law enforcement or other government agencies to the extent that they might demand personally identifiable information, should a certificate of confidentiality be sought from a federal or state agency to protect the research data and the identity of the subjects from subpoena or other legal process?
- Are there adequate plans to protect participants from the risks of breach of confidentiality and invasion of privacy? If the protocol involves an epidemiologic study, will subjects or their relatives be protected from learning inappropriate information?

VULNERABLE POPULATIONS [Refer to Additional Protections Forms]

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

- **Refer to the Additional Protections Forms for regulatory findings and determinations**.

CLINICAL INVESTIGATIONS OF DRUGS OR BIOLOGICAL PRODUCTS, OR MEDICAL DEVICES

- Is the research being conducted under an IND? If not, is an IND required? **[Refer to Drug Form]**
- Is the research being conducted under an IDE? If not, is an IDE required, i.e., is this a significant risk device study or a nonsignificant risk device study? **[Refer to Device Form]**
- Is this being conducted under a sponsor-investigator IND/IDE? If so, Partners Quality Improvement Program must meet with investigator to review responsibilities of IND/IDE holders, if they have not already done so.