

CRITERIA FOR APPROVAL

REGULATIONS FOR IRB REVIEW OF HUMAN RESEARCH

1. In accordance with 45 CFR 46.111 and 21 CFR 56.111, **all** of the following requirements must be satisfied in order to approve human subject research.

i. 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. Yes No

ii. 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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the knowledge on the community) but should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Yes No

iv. 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 regulations. Yes No N/A

v. Informed consent will be appropriately documented, in accordance with, and to the extent required by regulations. Yes No N/A

vi. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. Yes No

vii. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Yes No

2. 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. Yes No N/A

3. In order to approve research in which some or all of the subjects are children, an