APPENDIX 5.6

EVALUATION CRITERIA FOR PROPOSALS SUBMITTED TO THE COMMITTEE ON THE PROTECTION OF HUMAN SUBJECTS CALIFORNIA STATE UNIVERSITY, FRESNO

TITLE OF STUDY: _____

PRINCIPAL INVESTIGATOR: _____

COLLABORATORS: _____

DATE REVIEWED: _____

LEVEL OF RISK (AS ASSESSED BY THE PI): _____ Minimal Risk _____ At Risk

Criteria for IRB Approval of Research:

- ☐ Risks to subjects are minimized
- ☐ Risks to subjects are reasonable in relation to anticipated benefits
- ☐ Selection of subjects is equitable
- ☐ Informed consent is sought from each prospective subject or the subject's legally authorized representative
- ☐ Informed consent is appropriately documented and is adequate
- ☐ Where appropriate, research plan makes adequate provision for monitoring the data collected to insure the safety of subjects
- ☐ Adequate provisions to protect the privacy of subjects and maintain the data collected to insure the safety of subjects
- ☐ Where appropriate, safeguards are included in the study to protect the rights and welfare of vulnerable subjects

Elements of Informed Consent Present:

- ☐ Information given to the subject or legal representative is in understandable language
- ☐ Purpose of research (including larger social purpose, if appropriate)
- ☐ Procedures (including time involved and locale)
- ☐ Potential risks and discomforts
- ☐ Potential benefits
- ☐ Where applicable, alternative treatments contemplated (with risks and benefits)
- ☐ Extent of confidentiality
- ☐ Statement regarding voluntariness of participation and freedom to withdraw without jeopardy
- ☐ Assurance of investigator's readiness to answer questions (including phone number)
- ☐ Where applicable, terms of compensation
- ☐ When risk is a possibility, phone number to call if injured from participation
- ☐ Where applicable, provision for guardian or physician's consent

Decision: ☐ Approved ☐ Disapproved ☐ Convene a Meeting