Attachment 2

INSTITUTIONAL REVIEW BOARD PROTOCOL MODIFICATION REVIEW CRITERIA

All amendments to research protocols involving human subjects must be submitted to the Institutional Review Board for review and approval prior to implementing the activity describe in the amendment. As provided for in the federal regulations, "minor" administrative changes can be reviewed through an expedited process while the full committee will review "major" changes.
All amendment will be reviewed by the IRO staff and IRB Chair to determine whether it can be handled on an expedited basis or if it requires full board review.

Full Review Criteria:	**Expedited Review Criteria:**

• Increasing the physical and/or psychological risk/discomfort to the participant
• Major change in the design or goal of the study
• Making multiple changes in the protocol, instruments, and/or consent
• Adding a new consent form
• Expanding the eligibility criteria
• Increasing the number of participants at risk
• Adding questions asking for sensitive information e.g. depression or sexuality
• Adding an element that may breach the confidentiality of the participant (example: adding focus groups)
• Numerous modifications throughout the year where there may be confusion or a question as to the full scope of the study
• Whenever a study is closed for safety reasons e.g. FDA, DSMB, and/or PI initiated the closure will be referred to the full Board for review
• Gene Therapy Trial - unless minor administrative changes or the IRB Chair determines that the risk/discomfort is reduced to the participant.
	• Reduction of risk/discomfort to the participant
	• Adding or removing an institution
	• Changes to recruitment and advertising
	• Changes in the PI
	• Adding a questionnaire or instrument similar to the one already approved e.g. uses many of the same questions
	• Removing question from a questionnaire or instrument
	• Minor editorial modifications to the protocol, questionnaire, and/or consent that do not alter the meaning or procedure (spelling change, grammar, etc)
	• Consent form modifications that:
	  • Add or remove information from the consent form so that it is consistent with an already approved IRB requirement
	  • Defining a phrase more clearly in lay language
	  • Updating a consent form to use IRB approved boiler plate language

Please note that the above examples are presented as general guidelines only. Specific amendment classifications are made on a case-by-case basis.