

MODIFICATION REVIEW CHECKLIST

	Yes	No	Comments
A. Protocol:			
1. Is the purpose of the change summarized on modification form?			
2. Is the change reflected in the revised application?			
3. Does this change affect the purpose of the study?			
4. Does this change affect the procedures of the study?			
5. Is there justification for the change(s)?			
6. Does this change create the need for the study to be reviewed more frequently?			
B. Risk:			
1. Does this change affect the risk to subjects?			
2. Does this change affect the benefits to subjects or others?			
3. Does this change affect the risk/benefit relationship?			
C. Consent:			
1. Does the change affect the consent?			
2. Is the change reflected in the revised consent document(s)?			
3. Should subjects be re-consented?			
a. If so, has the PI provided an adequate plan for re-consenting subjects already enrolled?			
D. Other Concerns:			
2. Does the change affect the recruitment process?			
a. If so, is the recruitment process still appropriate?			
3. Does the change require a revised data safety plan?			
4. Does the change affect the privacy or confidentiality of subjects?			
a. If so, are the procedures to protect privacy and confidentiality still appropriate			
5. Does the change affect the protection of vulnerable subjects?			
a. If so, are the protections for vulnerable subjects still adequate?			