



**Review Checklist
Modification Review Checklist for Reviewers**

PI Name:	Reviewer:
Title of Protocol:	

Reviewer: Please check the following sections and detail all changes to be made below.

Type of Review (check one): <input type="checkbox"/> Full Board <input type="checkbox"/> Expedited * *If Expedited , indicate the appropriate category: _____	Recommendation (check one): <input type="checkbox"/> Approve as submitted <input type="checkbox"/> Deferred * <input type="checkbox"/> Disapprove* (for full board ONLY) * For deferral or disapproval , list reasons in the Changes, Changes, or Clarifications Section.
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Changes, Changes, and Clarifications

Please list any changes, changes, or clarifications required to the research protocol, informed consent form, or IRB application. If the research is to be deferred or disapproved, please also provide a brief explanation.

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?			