INSTRUCTIONS FOR RESPONSE

Please respond to this letter by doing the following:

1. The Response to Review document is located on the forms tab. **Please provide your COMPLETE answer to the question in this form in a different font.** Please also state the page number and document(s) which were changed in response to the question. The purpose of this "self contained response document" is to make it easy for the reviewers to fully understand your responses. Failing to follow these directions is likely to slow down review of your project. This format is not required for consent form changes, where it is fine to make the changes and submit the revised consent form with deletions in red strike-through, and additions in yellow highlighting.
2. Incorporate into the Protocol Summary and any other relevant study documents the changes outlined in this memo as well as any other changes made to address the Committee's questions and concerns about the study. Please submit clean and marked up copies of the revised document(s). This will facilitate the review of your response. Revising documents ensures that the study is conducted according to the updated Protocol and will facilitate continuing review.