Review Date of PI’s Response:

Protocol Title:

Principal Investigator:

Protocol Version Number & Date:

Sponsor:

Response Type: [ ]  Point-by-Point Response Only

[ ]  Point-by-Point Response with Protocol Modification:

 Revised Protocol Version Number & Date:

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Concerns that Must be Addressed Before Approval

1) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

2) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

3) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

4) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

5) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

6) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

7) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

8) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

9) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

10) Original Concern:

 PI’s Response:

 Is response acceptable? [ ]  No

 [ ]  Yes

 Comments:

Suggestions (response not required)

1) Original Suggestion:

 PI’s Response:

 Comments:

2) Original Suggestion:

 PI’s Response:

 Comments:

3) Original Suggestion:

 PI’s Response:

 Comments:

4) Original Suggestion:

 PI’s Response:

 Comments:

5) Original Suggestion:

 PI’s Response:

 Comments:

6) Original Suggestion:

 PI’s Response:

 Comments:

7) Original Suggestion:

 PI’s Response:

 Comments:

8) Original Suggestion:

 PI’s Response:

 Comments:

9) Original Suggestion:

 PI’s Response:

 Comments:

10) Original Suggestion:

 PI’s Response:

 Comments:

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**Study Disposition:**

**[ ]  Approval**

**[ ]  Deferred for Revision**

[ ]  **Disapproval**

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Chair or Co-Chair Signature Date

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Print Name of Chair or Co-Chair