**PRMC PROTOCOL EVALUATION FORM – Protocol Development Ad Hoc Review**

PROTOCOL NUMBER:

PI:

A. Does the schema match the protocol design? [ ]  [ ]  [ ]

 Yes No N/A

B. Are the study objectives measurable and reportable? [ ]  [ ]

 Yes No

C. Are standard eligibility criteria present? [ ]  [ ]

 Yes No

D. Is standard registration language present? [ ]  [ ]

 Yes No

E. Are dose modifications clear and comprehensive? [ ]  [ ]  [ ]

 Yes No N/A

1. Is AE reporting language appropriate to study scope? [ ]  [ ]

 Yes No

1. Does study calendar match narrative? [ ]  [ ]  [ ]

 Yes No N/A

1. Is Data Submission schedule present and consistent? [ ]  [ ]  [ ]

 Yes No N/A

1. Is research specimen collection adequately described? [ ]  [ ]  [ ]

 Yes No N/A

1. Is DSM plan adequate and appropriate? [ ]  [ ]

 Yes No

1. If multicenter, are requirements described? [ ]  [ ]  [ ]

 Yes No N/A

RECOMMENDATION: Approved [ ]  Contingent [ ]  Deferred [ ]  Disapproved [ ]

Overall Critique: