# PRMC PROTOCOL EVALUATION FORM – Physician Scientific Review (Primary)

PROTOCOL NUMBER:

PI:

 **Satisfactory Unsatisfactory**

1. Research Problem

1. Background and Rationale [ ]  [ ]

2. Objectives and/or Hypothesis [ ]  [ ]

1. Design Characteristics

1. Subject Assignment [ ]  [ ]

2. Trial Period [ ]  [ ]

3. Feasibility of Enrollment [ ]  [ ]

1. Treatment Characteristics

1. Dose, Duration, Route [ ]  [ ]

2. Toxicity [ ]  [ ]

1. Subject Characteristics
2. Selection Criteria [ ]  [ ]
3. Representative [ ]  [ ]
4. Inclusion/Exclusion of Children [ ]  [ ]
5. Data Collection

1. Schedule-Study Calendar & Forms [ ]  [ ]

1. Statistics

1. Endpoints Clearly Defined [ ]  [ ]

2. Objectives achievable [ ]  [ ]

 G. Data safety and monitoring plans [ ]  [ ]

Reviewer Notes:

Overall Critique:

Please list the comments/ recommendations needed for approval:

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