**PRMC PROTOCOL EVALUATION FORM – Physician Scientific Review (Secondary)**

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