**PRMC PROTOCOL EVALUATION FORM – Biostatistical Reviewer**

PROTOCOL NUMBER:

PI:

 **Satisfactory Unsatisfactory**

1. Research Problem

1. Background and Rationale [ ]  [ ]

2. Objectives and/or Hypothesis [ ]  [ ]

1. Design Characteristics
2. Independent Variables [ ]  [ ]
3. Design Configuration [ ]  [ ]
4. Subject Assignment [ ]  [ ]
5. Control of Treatment-Related Bias [ ]  [ ]
6. Control of Extraneous Variables [ ]  [ ]
7. Dependent Variables [ ]  [ ]
8. Trial Period [ ]  [ ]
9. Treatment Characteristics

1. Dose, Duration, Route [ ]  [ ]

2. Toxicity [ ]  [ ]

1. Subject Characteristics

1. Selection Criteria [ ]  [ ]

1. Representative [ ]  [ ]
2. Data Collection
3. Scope [ ]  [ ]
4. Quality Assurance [ ]  [ ]
5. Schedule [ ]  [ ]
6. Data Analysis
7. Data Preparation [ ]  [ ]
8. Statistical Analysis [ ]  [ ]
9. Sample Size [ ]  [ ]
10. Data safety and monitoring plans

**PHASE II Trials**: Are the stopping rules adequate? Yes [ ]  No [ ]

**PHASE II Trials**: Will an interim analysis be conducted? Yes [ ]  No [ ]

 Does the study require audit by QASMC? Yes [ ]  No [ ]

 Does the study require a DSMC? Yes [ ]  No [ ]

 Should the DSM report be internal or external? Internal [ ]  External [ ]

Reviewer Notes:

Overall Critique:

Please list the comments/ recommendations needed for approval:

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