**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