Scientific Reviewer Guidelines for Preparing Written Comments

**Description:**
- Concisely describe the protocol, including aims, procedures, and background.

**CRITIQUE:**
- Discuss the strengths and weaknesses of the protocol.
- Is the protocol clearly written?
- Is the methodology adequate to answer the questions posed?
- Has sufficient considerations been given to the statistical aspects of the protocol?
- Is the Standard Monitoring Plan included in the protocol or abstract?

**Departmental Review (Content Expert Reviewer Only):**
- In addition to the above, please summarize comments and/or critiques from the department review process that supported the protocol’s approval. Please also include overall results of scoring, vote tally and/or prioritization ranking within the department.

**Required Appendices:**
- Is the Prioritization List appropriate for the disease site?
- Is the protocol listed on the Prioritization List?
- Is the Protocol Checklist completed?

Prepare a critique addressing the relative research benefits and the potential risks to the participant. State whether you consider the research to be justifiable. Potential risk to the participant should never exceed the potential benefits to the advancement of research. Provide any suggestions that might improve the protocol.

**Recommendation:**
Summarize your evaluation into a specific recommendation.