



JOINT CLINICAL TRIALS OFFICE (JCTO)

**Clinical Study Evaluation Committee (CSEC)
Principal Investigator Score and Signature Sheet**

PI Name:

Title:

IRB Protocol Number:

Please evaluate your study based on the following categories and provide the appropriate signatures for this submission. Please scan and upload this completed document to the PI Score and Signatures Section of the electronic CSEC Submission Form Part B.

REVIEW SCORES: 1 (FAVORABLE) TO 4 (UNFAVORABLE)

CATEGORIES:

A. SCIENTIFIC MERIT:

- 1 High importance, with correlative/translational analysis
- 2 Intermediate importance with correlative/translational analysis
- 3 Intermediate importance without correlative/translational analysis
- 4 Low priority, including Phase IV

Comments:



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B. STATISTICAL CONSIDERATIONS:

- 1 Endpoints and sample size well calculated; expected overall study accrual realistic
- 2 Endpoints and sample size well calculated; expected overall study accrual questionable, or minor statistical issues.
- 3 Endpoints suboptimal and/or statistical plan problematic
- 4 No statistical plan or insufficient statistical plan

Comments:

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C. INVESTIGATOR ROLE IN STUDY DESIGN:

- 1 Cornell Investigator-initiated design; NIH/Grant funded
- 2 Cornell Investigator-initiated design; pharmaceutical or non-sponsored
- 3 Cornell Investigator involved in design. Please explain role below.
- 4 Cornell Investigator minor or no role in design

Comments:



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D. EXPECTED CORNELL ACCRUAL

- 1 Extensive track record in similar populations
- 2 Moderate track record in similar populations
- 3 No prior attempts of accrual in similar populations
- 4 Poor track record in similar populations

Comments:

E. FINANCIAL/BUDGET

- 1 Favorable
- 2 Reasonable
- 3 Marginally acceptable
- 4 Unfavorable

Comments:



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F. PROGRAMMATIC CONSIDERATIONS / STUDY SIGNIFICANCE

- 1 Addresses compelling programmatic needs
- 2 Addresses substantive programmatic needs
- 3 Addresses minimal programmatic needs
- 4 Programmatic needs argue against trial initiation as proposed

Comments:

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Has this study been discussed with and approved by your disease area leader/division chief/department chair? """"""""

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If yes, please provide the name of that individual in the space below.

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As Principal Investigator, I attest that I have reviewed all information in this CSEC REDCap application Part A and Part B and approve this application for submission.

PI Signature: _____

Date: _____