Clinical Study Evaluation Committee (CSEC)

Reviewer Checklist

The Clinical Study Evaluation Committee (CSEC) emphasizes the following while reviewing proposals:

Scientific Merit:

☐ There is a clearly stated purpose or question to address that will be the focus of the project.

☐ Adequate background information is provided and supports the overall study plan.

☐ Experimental design and methodology are appropriate to answer the purpose/question and are sufficiently detailed.

☐ Testing procedures are appropriate to the proposed population and are adequate to answer the research question (including inclusion and exclusion criteria).

☐ Statistical analysis is appropriate to the experimental design and methodology.

☐ Outcome measures/study endpoint are valid, appropriate and will answer the research question.

☐ Comprehensive literature review is provided as needed.

Feasibility:

☐ A comprehensive, realistic and cost-effective budget is outlined.

☐ The outlined time frame for completion is realistic.

☐ Research procedures are clearly differentiated from standard of care procedures.

☐ Rationale for the number of subjects to be recruited is justified.

☐ Applicant team's research experience, credentials and institutional and program environment are adequate to manage and implement the entire project.

☐ Applicant team's credentials and/or experience are strong, not only for the purposes of carrying out the project, but to increase the probability of publication in a peer-reviewed journal.

☐ Safety/facility considerations to minimize risk are communicated.
Study Significance:

☐ The importance of participation in this project for the PI is clearly stated.

☐ Participation in the project is expected to improve the PI’s standing in the research community.

☐ Participation is integral to ongoing research as part of the PI's research program.

☐ Project serves programmatic needs.

☐ The impact of the project on the field is clearly stated and significant.

Informed Consent:

☐ Not applicable, this study appropriately requests a waiver of informed consent.

☐ Study drugs or devices are identified.

☐ Drug or device status with the FDA is clearly stated.

☐ Known risks of the drug or device are clearly stated.

☐ Known risks seem reasonable in relation to potential benefits to subject or to the importance of knowledge that may result from the research.

☐ Costs to the subject are clearly defined.

☐ Alternative options are comprehensive and clearly identified.

☐ The procedures outlined in the consent form match those listed in the protocol or Non-Technical Research Plan.