Weill Cornell Medical College NewYork-Presbyterian

JOINT CLINICAL TRIALS OFFICE (JCTO)

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.