**PIEC Application Form Annex A – Placebo Usage**

PROTOCOL TITLE:

Text Field

1) Explain what ‘standard of care’ therapy is available for this condition.

Text Field

*2) Discuss the ethical implications of using placebo instead of ‘standard of care’ therapy in this situation.*

Text Field

*3) Address the issues of safety and efficacy of other available therapies.*

Text Field

*4) What is the total duration the study participants would be on placebo arm of the study?*

Text Field

5) What is the greatest potential harm that the study participants might be exposed to as a result of not receiving effective therapy?

Text Field

*6) What are the procedures in place to safeguard study participants receiving placebo?*

Text Field

7) Any other comments supporting the use of placebo in this study?

Text Field