**Protocol Review Template:**

  1. Describe the primary objectives of the study. Are the research questions well defined? Is there a distinction between the objectives and the outcome measures? Have the outcomes been clearly defined? Will the data collected provide information to answer the research questions?

2. Are the key sections of the protocol, including the background, eligibility criteria, study design, study calendar, methodology, and any other key sections, written clearly and adequately to answer the study objectives? Describe in a few sentences and raise any questions or comments regarding these sections.

3.  Describe the study design in a paragraph or less. Then answer the following questions:

a. Is the design of the study appropriate?

b. Have issues relating to patient drop-out, ineligibility or patient screening been addressed, if applicable?

c. Is the design supported by the preliminary studies and data presented?

d. Are there suggestions you would make for improving the study to better address the research questions?

4. Describe the analysis plans, briefly, for answering the primary objective. Will the data collected and analyses proposed answer the primary and secondary objectives of the study?

5.  How is the sample size of the study justified? Are you convinced that the sample size proposed is appropriate (i.e. not too small, not too big)? Consider statistical and practical considerations regarding sample size, phase of study and possibly accrual challenges.

6. Describe any early stopping rules or safety monitoring to ensure safety of patients and the ethics of the continuing (or stopping) the study if unexpected adverse events occur. Do you feel that patient safety is protected and appropriately monitored?