Instructions: IRB Members and IRB administrators/analysts may utilize this tool as a guidance when reviewing investigator initiated pragmatic (i.e., comparative effectiveness) clinical trials. Utilize this tool in combination with the July 2018 IRB member training slides available online here: <https://irb.upenn.edu/mission-institutional-review-board-irb/irb-member-toolbox>

**Study Necessity / Contribution**

1. Does the literature review and background support that this study has clinical equipoise? Is there a need for this study to be conducted?
2. Is there an appropriate plan for dissemination?
3. Does the literature review and background support that this study will contribute to generalizable knowledge?
   1. Will the study provide valuable evidence that may benefit future patients?
   2. Has all of the literature available been considered? If continuing review is being considered, has recent literature been assessed by the team?

**Study Design: Usual Care**

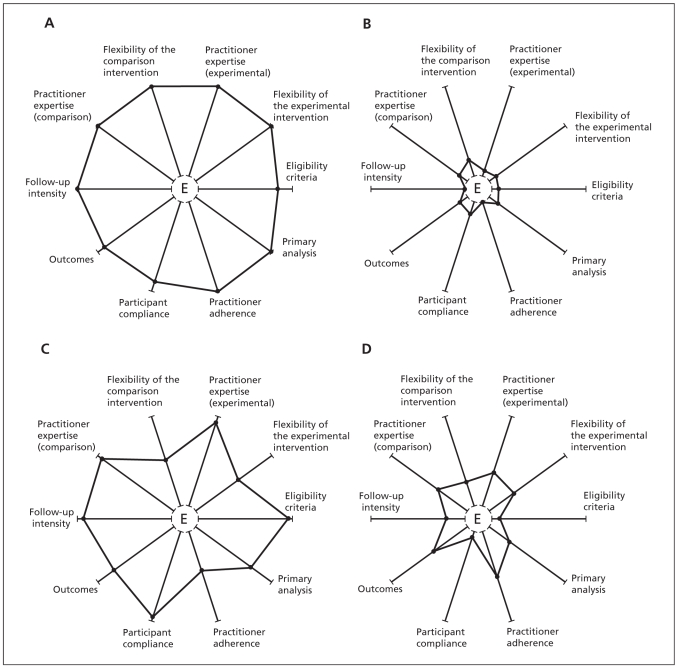
1. Does the literature review and background appropriately justify that the intervention is usual care? Are more citations or a consultation with an expert necessary?
2. Is there a difference in how the usual care intervention is being administered on this protocol compared to usual care outside of the context of this study? (e.g., Has a continuum been bifurcated into groups? Are usual care extremes being compared?)

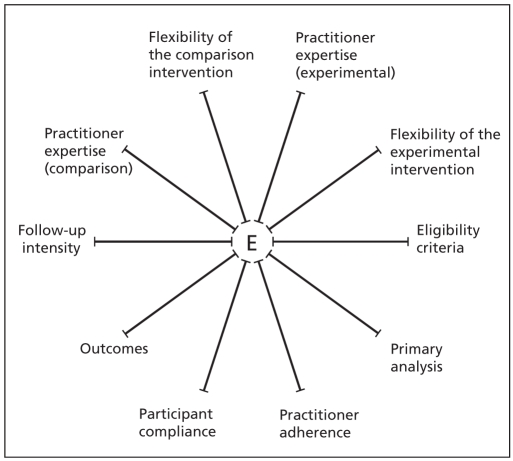
**Study Design: Research Elements**

1. Does the study involve randomization?
2. Does the study involve blinding?
3. How controlled is the trial design?
   1. Are physicians freely able to use their personal clinical judgement in the patient’s care?
   2. Will patients be able to switch treatments during the study?
   3. How will this impact the results of the study?

**Study Design: Pragmatic versus Explanatory**

1. On the continuum of explanatory to pragmatic, where does this study lie? Utilize the Pragmatic Explanatory Continuum Indicator Summary (PRECIS) Wheel (Thorpe et al., 2009) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2679824/>. Below is an example of how to complete the wheel. A and C are more pragmatic whereas B and D are more explanatory. E = Explanatory.





1. Based on the review, does the intervention constitute usual care or research? Note: If study is more explanatory and the intervention has been determined to be research, ethical regulations and principles apply to that intervention.

**Risks are Minimized / Adequate Provision for Monitoring the Data**

1. Would interim analysis with a plan to terminate the study be appropriate?
2. Does the study require a Data Safety Monitoring Committee or Board to review the study data?

**Informed Consent**

1. Is a full research informed consent process and form necessary?
2. If the study is minimal risk and the team is requesting a waiver of consent: Could an alternative consent model such as integrated, targeted, or broadcast consent be considered?
3. Should standard care procedures be delineated in the consent form, or would it suffice to refer to a clinical consent form / process?
4. Should the risks /benefits of usual care treatments be delineated in the consent form?
   1. If not, should a statement be included that notes that it is unknown if the risks /benefits between the two treatments differ?