

## **Approach Section Instructions:**

Please include all of the following in your proposal (**Limit: 2,000 words**):

- **Aims and Outcomes** (clearly defined; no more than one primary outcome, 2-5 secondary outcomes, and 3-5 tertiary outcomes). Each aim should include a hypothesis.
- **Inclusion Criteria**
- **Exclusion Criteria**
- **Variables to be collected** (present in a table format with definitions for any variables that are not inherently obvious; include the table at the bottom of the proposal).
- **Statistical Analysis Plan**
  - a. **Statistical tests that will be used to evaluate the hypotheses, including:**
    - Continuous data
    - Categorical data
    - Survival data
    - Repeated measures data
    - Adjustments for multiple comparisons (e.g., Bonferroni correction)
  - b. **Sample size justification and power analysis, including:**
    - Effect size
    - Type I error ( $\alpha$ )
    - Power (typically 80–90%)
  - c. **Handling of missing data**
  - d. **Confounding and bias control, including:**
    - Stratification
    - Regression modeling
    - Propensity score matching
  - e. **Planned subgroup analyses and sensitivity analyses**
  - f. **Software to be used**