RESEARCH PROPOSAL TEMPLATE

Project Title

Provide the title of the proposed study. This should include a description of the study design and main outcome of interest.

Character Limit*: 150

Narrative Summary

Provide a plain English summary of the proposed study that is suitable for a general or lay audience, clarifies the design, and explains the relevance of the research project to science and public health.

Character Limit*: 700

Scientific Abstract

Provide a structured abstract for the proposed study, using the following sub-headings: Background; Objective; Study Design; Participants; Main Outcome Measure(s); and Statistical Analysis.

Character Limit*: 1,600

Brief Project Background and Statement of Project Significance

Provide a brief summary of the research project’s background, including a clear description of the project’s significance and how information gained from this work will be used to create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health. Provide references to prior work on the topic if applicable at the end of the proposal.

Character Limit*: 3,200

Specific Aims of the Project

Provide a concise description of the specific aims of the project, including the study objectives and the specific hypotheses to be evaluated.

Character Limit*: 1,300

What is the purpose of the analysis being proposed? Please select all that apply.

- New research question to examine treatment effectiveness on secondary endpoints and/or within subgroup populations
- New research question to examine treatment safety
Research that confirms or validates previously conducted research on treatment effectiveness
- Research that confirms or validates previously conducted research on treatment safety
- Preliminary research to be used as part of a grant proposal
- Summary-level data meta-analysis:
  - Summary-level data meta-analysis uses only data from YODA Project
  - Summary-level data meta-analysis will pool data from YODA Project with other additional data sources
- Participant-level data meta-analysis:
  - Participant-level data meta-analysis uses only data from YODA Project
  - Participant-level data meta-analysis will pool data from YODA Project with other additional data sources
- Other
  - Please explain

Research Methods

In the fields below, provide a clear description of the research methods to be used to address each of the specific aims posed. Extensive statistical detail is not required; however, you should outline the general analytic approach and describe any conceptual models and causal relationships, potential confounders, subgroup and interaction analysis that will be included. Vague descriptions such as “adjust for all significant variables” and blind variable selection methods (e.g., stepwise selection) are strongly discouraged. Provide references for any novel or non-standard methods at the end of this proposal. Be specific and concise.

Data Source and Inclusion/Exclusion Criteria to be used to define the patient sample for your study

Character Limit*: 4,000

Main Outcome Measure and how it will be categorized/defined for your study

Character Limit*: 1,200

Main Predictor/Independent Variable and how it will be categorized/defined for your study

Character Limit*: 1,200

Other Variables of Interest that will be used in your analysis and how they will be categorized/defined for your study

Character Limit*: 1,200
Statistical Analysis Plan

Describe how you will analyze the requested clinical trial data, including descriptive, bivariate and multivariable analyses, and any other planned advanced analyses (such as propensity score methods, Kaplan-Meier or Cox modeling approaches, non-parametric testing).

Character Limit*: 1,700

Project Timeline

Provide an estimation of key milestone dates for the proposed study, including anticipated project start date, analysis completion date, date manuscript drafted and first submitted for publication, and date results reported back to the YODA Project. Please note: if your data request is approved, the Data Use Agreement allows for access for a 12 month period, with the possibility of an extension.

Character Limit*: 1,300

Dissemination Plan

Provide a description of anticipated products and target audience(s), including expectation for study manuscript(s) and potentially suitable journals for submission of the completed research project.

Character Limit*: 1,300

Bibliography

Provide references for all cited material.

Character Limit*: 13,000

*Character limits include spaces