



Yale University Open Data Access (YODA) Project



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

Research Proposal

Please provide a clear and succinct description of your Research Proposal. This information will be used by the YODA Project to determine the scientific merit of the proposed work. Please ensure that the scientific purpose is clearly described, clarify how the data requested will be used to create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health, and be sure that the proposed research can be reasonably addressed using the requested data. Scientific review by peer experts and/or members of the YODA Project Steering Committee may be solicited if the YODA Project is unable to verify the scientific merit of the proposal. If the request is approved, all information will be made publicly available on the YODA Project website at the time of data access. The YODA Project encourages applicants to develop their proposals in Microsoft Word and copy/paste the proposal directly into the spaces provided below.

Scientific Abstract

Provide a structured abstract for the proposed study, using the following sub-headings: Background; Objective; Study Design; Participants; Primary and Secondary 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.



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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 your Study Design? Please select one of the following options.

- Individual trial analysis
- Meta-analysis (analysis of multiple trials together)
- Methodological research
- Other
 - Please explain

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
- Confirm or validate previously conducted research on treatment effectiveness
- Confirm or validate previously conducted research on treatment safety
- Preliminary research to be used as part of a grant proposal
- Summary-level data meta-analysis
 - Meta-analysis using only data from the YODA Project
 - Meta-analysis using data from the YODA Project and other data sources
- Participant-level data meta-analysis
 - Meta-analysis using only data from the YODA Project
 - Meta-analysis using data from the YODA Project and other data sources
- Develop or refine statistical methods
- Research on clinical trial methods
- Research on comparison group
- Research on clinical prediction or risk prediction
- 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

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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. Please consider the following when drafting methods: Approved investigators will be granted access to participant-level data sets via a remote, secure, password-protected data sharing platform. All work on the data must take place within the secure platform. The platform will be easily accessible to researchers, and ongoing system monitoring and support will be available. Within the platform, researchers will have access to the following analytical tools: Stata, R, RStudio, and Open Office. If needed, researchers will be able to upload additional data sets to the secure platform, if the researcher has the rights/license to do so. Supporting documentation, such as CSRs, as well as summary analyses, will be downloadable from the platform. The YODA Project will work with researchers to ensure that projects can be conducted within the platform.

Software to be used:

- Python
- R
- RStudio
- STATA
- Open Office
- I am not analyzing participant-level data / I plan to use another secure data sharing platform
 - Please clarify:

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

For the trials made available through the YODA Project, list the explicit inclusion and exclusion criteria (i.e.: demographic/clinical characteristics) that will be applied to the patients in each trial to define your study sample. If no exclusion criteria, state ‘None.’ If you plan to use data from studies other than those being requested through the YODA Project, please specify which other studies you will be using and from where you will be obtaining the data from these other studies. If you plan to pool these data with data from the YODA Project for analyses, please clarify on what platform you will be conducting the IPD analysis or if you are aggregating summary results.

Character Limit*: 1,200

Primary and Secondary Outcome Measure(s) and how they will be categorized/defined for your study

Specify **all** primary outcome measure(s) and, when applicable, **all** secondary outcome measure(s) of your study, i.e., the endpoints on which your study is focused, ensuring they are clearly defined and can be readily compared to your final analysis reported in a publication. If no secondary outcome measure(s) will be considered, please clarify.



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When applicable, please also describe any changes to the primary and/or secondary outcome measure(s) in the final analysis reported in your publication.

Character Limit*: 1,200

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

Clearly define the main independent variable(s) for your study, i.e., the variable being tested for an independent effect on the primary and secondary outcome measure(s), ensuring the variable is clearly defined and can be readily compared to your final analysis reported in a publication.

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

Clearly define all other variable(s) that will be used in analysis, either to characterize the study sample and/or for purposes of multivariable risk adjustment, including variable definitions as needed.

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*: 4,000

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

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Provide references for all cited material.

Character Limit*: 13,000

*Character limits include spaces

Supplementary Material

If there is any additional information you want to include to supplement your Research Proposal, such as a published protocol, please add this using the Upload button below and click Save. Please note: the YODA Project prefers a blinded review. If the researcher wishes to remain anonymous to reviewers, all documentation provided within this section must be fully redacted by the researcher.