|  |  |
| --- | --- |
| Title of Study or Project: | Enter Title of Study or Project |
| Primary Institution: | Enter Primary Institution |
| Primary Author: | Enter Primary Author |
| Co-Authors: | Enter Co-Authors |
| Statistician(s): | Enter Statistician(s) at MPOG active site |
| Type of Study: | Exploratory/Retrospective Observational/Prospective Trial/Other (Describe) |
| Data Source(s): | MPOG Database / STS / NSQIP / Other (Describe) |
| IRB Number/Status: | IRB Number/ Choose a status  If submitted, verify the following:  IRB is specific to this project  IRB specifies that dataset is a limited dataset (i.e., not de-identified)  PI is listed on the study IRB |
| Hypotheses / Aims: | Hypotheses/Aims, please be sure to describe how you plan to define your cohort, exposure, and outcome |
| Number of Patients/Participants: | Please list the cohort sample size estimated using MPOG DataDirect |
| Power Analysis: | Enter power analysis results |
| Proposed statistical tests/analyses: | Enter proposed statistical analyses |
| Resources (Brief summary of resources for data collection, personnel, financial): | Enter Summary |

**\*\*STOP \*\***

*Before investing the substantial time to develop the rest of this proposal, please submit the Cover Sheet to the MPOG Coordinating Center via the ‘****Research Consultation Form,’*** *as detailed in Step 3 of the MPOG website -->  Research -->  “*[*Research Proposal Process*](https://mpog.org/write-a-research-proposal/)*” .*

Submission of the Cover Sheet enables the MPOG Central Research Team to provide early feedback on your project idea, in its formative stages, in order to:

1. ensure feasibility;
2. identify potential collaborators across MPOG who are developing similar projects;
3. position your project for maximal chance of successful publication in a high-impact journal.

Please note, successful completion of an MPOG project typically requires an integrated team-based scientific approach with:

* ***Clinical subject matter expertise*** (usually with a primary medical qualification and perioperative clinical practice insight), and
* ***Statistical methods expertise*** (usually with doctoral level training and experience in public health science, e.g. biostatistics, epidemiology)

Please consider seeking collaboration from those with complementary expertise to ensure these skills are reflected in your study team.

The remainder of this template includes all the sections necessary to complete your PCRC proposal. Please include all the following sections as applicable to your project.

The MPOG Central Research team is committed to your success!

# Introduction

Enter text. Target 300-500 words (limit 750 words) to cover the significance, current gaps, and how project will address this gap. What are the aims and hypotheses?

# Methods

## Study Design

Enter text. Include the type of study, IRB approval statement, and reporting guidelines to be followed.

## Study Population

Enter text. Include the date range, selection criteria for institutions, specify whether non-US institutions should be included, and inclusion/exclusion criteria to be applied to identify the study population. Include an estimate of your sample size as determined by MPOG DataDirect or preliminary data analysis.

## Data source

Enter text to indicate your data source. MPOG database may be sufficient for this section. If you anticipate using other sources, state how your propose to link them to the pooled MPOG dataset.

### Primary outcome

Enter text to clearly define the primary outcome.

### Secondary outcome(s), if applicable

Enter text to clearly define the secondary outcome(s).

### Exposure Variable, if applicable

Enter text to clearly define the exposure variable, if applicable

### Covariates

Enter text or table to clearly indicate relevant covariates, these should be consistent with the query specification.

## Statistical analysis

Enter text to clearly describe rigorous pre-specified statistical analysis plan. Include planned sensitivity or subgroup analyses, and analyses of secondary outcomes, in addition to primary analyses.

### Power analysis

Enter text to describe power analyses (required for primary aim)

## Handling of missing, invalid, or extreme value data

Enter text to describe how you will define and handle artifacts, abnormal/extreme or missing values. In particular, for your exposure and outcome variables.

## Major Threats to Inference & Mitigation Strategies

Enter text to describe major threats to inference that may affect your proposed analysis and your plans to mitigate these threats.

# Preliminary Data Analyses

Provide the results of preliminary data analyses from your local institution that supports the key assumptions underlying your choice of exposure and outcomes in this study.

# Areas for discussion / Known Limitations

* List additional points you wish to discuss at the PCRC meeting.

# References

# Reporting Guidelines Checklist

For convenience, the most common checklist for MPOG studies – the [RECORD extension](#RECORD) of the STROBE guidelines – is listed below, but please replace with the appropriate checklist if needed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Item No.** | **STROBE items** | **Page #** | **RECORD items** | **Page #** |
| **Title and abstract** | | | | | | |
|  | 1 | (a) Indicate the study’s design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found |  | RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.  RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract.  RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract. |  |
| **Introduction** | | | | | | |
| Background rationale | 2 | Explain the scientific background and rationale for the investigation being reported |  |  |  |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses |  |  |  |
| **Methods** | | | | | | |
| Study Design | 4 | Present key elements of study design early in the paper |  |  |  |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |  |  |  |
| Participants | 6 | *(a) Cohort study* - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  *Case-control study* - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls  *Cross-sectional study* - Give the eligibility criteria, and the sources and methods of selection of participants  *(b) Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed  *Case-control study* - For matched studies, give matching criteria and the number of controls per case |  | RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided.  RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided.  RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage. |  |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. |  | RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided. |  |
| Data sources/ measurement | 8 | For each variable of interest, give sources of data and details of methods of assessment (measurement).  Describe comparability of assessment methods if there is more than one group |  |  |  |
| Bias | 9 | Describe any efforts to address potential sources of bias |  |  |  |
| Study size | 10 | Explain how the study size was arrived at |  |  |  |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why |  |  |  |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding  (b) Describe any methods used to examine subgroups and interactions  (c) Explain how missing data were addressed  (d) *Cohort study* - If applicable, explain how loss to follow-up was addressed  *Case-control study* - If applicable, explain how matching of cases and controls was addressed  *Cross-sectional study* - If applicable, describe analytical methods taking account of sampling strategy  (e) Describe any sensitivity analyses |  |  |  |
| Data access and cleaning methods |  | .. |  | RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population.  RECORD 12.2: Authors should provide information on the data cleaning methods used in the study. |  |
| Linkage |  | .. |  | RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided. |  |
| **Results** | | | | | | |
| Participants | 13 | (a) Report the numbers of individuals at each stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed)  (b) Give reasons for non-participation at each stage.  (c) Consider use of a flow diagram | ***N/A for PCRC*** | RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram. | ***N/A for PCRC*** |
| Descriptive data | 14 | (a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders  (b) Indicate the number of participants with missing data for each variable of interest  (c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount) | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Outcome data | 15 | *Cohort study* - Report numbers of outcome events or summary measures over time  *Case-control study* - Report numbers in each exposure category, or summary measures of exposure  *Cross-sectional study* - Report numbers of outcome events or summary measures | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included  (b) Report category boundaries when continuous variables were categorized  (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Other analyses | 17 | Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| **Discussion** | | | | | | |
| Key results | 18 | Summarize key results with reference to study objectives | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |  | RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported. |  |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | ***N/A for PCRC*** |  | ***N/A for PCRC*** |
| **Other Information** | | | | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based |  |  |  |
| Accessibility of protocol, raw data, and programming code |  | .. |  | RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code. |  |