Protocol Templates for Literature Reviews and Secondary Analysis

When seeking approval for systematic/scoping reviews or projects using secondary data analysis, the relevant template must be completed and included as an appendix as part of your application to CPREC.

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# Protocol of a systematic/scoping review

Note that there are several types of review possible and this protocol may need adjustment. Discuss adaptations of this form with your supervisors and Research Director if needed.

This form must be accompanied by a Data Management Plan and Ethics Application (for systematic /other review formats).

**Review title.** Provide the working title of the review.

**Anticipated start date. Anticipated completion date.**

**Collaborators and Co-authors**

Give the names and role of each member of the review team and indicate their role on the review ( e.g. second reviewer, clinical advisor).

**Funding sources/sponsors.**

**Conflicts of interest.**

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review. Financial relationships (e.g. employment, consultancies) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the review.

**Review question.**

State the question(s) to be addressed by the review, clearly and precisely.

**Searches.**

* State the sources that will be searched.
* Indicate any restrictions (e.g. language or publication period).
* Indicate if studies using only qualitative or only quantitative methods will be included, or if both types will be included with brief rationale.
* Name all sources that will be used to identify studies for the systematic review. Sources include (but are not limited to) bibliographic databases, reference lists of eligible studies and review articles, key journals, conference proceedings, trials registers, Internet resources and contact with study investigators, experts and manufacturers.
* What are the search dates (from and to)?
* Are there any restrictions on the search including language and publication period?
* Will searches will be re-run prior to the final analysis?
* Will you seek any unpublished studies?
* Indicate the type of search tool/question framework proposed for review: PICO(S), SPIDER, SPICE, ECLIPSE etc. Briefly describe the rationale to be offered on how this most appropriately answers the research question.

**Condition or domain being studied.**

* Give a short description of the condition/experience/topic being studied. This could include health and wellbeing outcomes. Example: aggression in children.

**Participants/population.**

* Give summary criteria for the participants or populations being studied by the review, including details of both inclusion and exclusion criteria. Example: Inclusion: Adults with schizophrenia (as diagnosed using any recognised diagnostic criteria). Exclusion: Adolescents (under 18 years of age) and elderly people (over 70).

**Intervention(s), exposure(s).**

* If an intervention or exposure is being studied, give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed. If appropriate, an operational definition describing the content and delivery of the intervention should be given.
* For reviews of qualitative studies give details of the focus of the review.

**Comparator(s)/control.**

* If applicable, give details of the alternatives against which the main intervention/programme/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.
* Systematic reviews of qualitative studies rarely have a comparator or control and it is acceptable to note ‘Not applicable’.

**Types of study to be included.**

* Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.
* If different study designs are needed for different parts of the review, this should be made clear. Where qualitative evidence will be incorporated in or alongside a review of quantitative data, this should be stated.
* **Example:** We will include randomised trials to assess the beneficial effects of the treatments, and will supplement these with observational studies (including cohort and case–control studies) for the assessment of other effects.

**Main outcome(s).**

* Give the pre-specified primary (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria. Example:Change in depression score from baseline to the last available follow-up, measured using the Beck Depression Inventory.
* For systematic reviews of qualitative studies give details of what the review aims to achieve.

**Data extraction (selection and coding).**

* Describe how studies will be selected for inclusion.
* State what data will be extracted or obtained. State how this will be done and recorded.
* Data extraction methods reported in systematic review protocols should include:
* Study selection
* The number of reviewers applying eligibility criteria and selecting studies for inclusion in the systematic review
* (good practice is more than one person) and how this will be done (e.g. independent screen of records for inclusion; one screener, one verifying decisions) and whether the decisions are ‘blind’, that is researchers will be blinded to each other’s’ decisions.
* How disagreements between individual judgements will be resolved
* The software system or mechanism for recording decisions
* Data extraction
* List which data will be extracted from study documents, including information about study design and methodology, participant demographics and baseline characteristics, numbers of events or measures of effect (where applicable).
* Alternatively, state how this information will obtained from study investigators.
* The number of people extracting or checking received data (good practice suggests more than one individual) and how this will be done (e.g. whether two people will independently extract data or whether one will extract data and an other person check the extracted data).
* How disagreements between individual judgements will be resolved
* How missing data will be handled including whether study investigators will be contacted for unreported data or additional details.
* The means of recording data (e.g. in an Excel spreadsheet, Rayyan software or other software)

**Risk of bias (quality) assessment.**

* Describe the method of assessing risk of bias or quality assessment. State which characteristics of the studies will be assessed and any formal risk of bias tools that will be used.
* Methods for assessing risk of bias reported in systematic review protocols should include:
* Which characteristics will be assessed (e.g. methods of randomisation, treatment allocation, blinding).
* Whether assessment will be done at study or outcome level
* The criteria used to assess internal validity, if formal a risk of bias assessment is planned (e.g. the Cochrane risk of
* bias tool).
* How the results of the assessment will inform data synthesis (where applicable).
* The number of reviewers that will be involved in the quality assessment
* How disagreements between reviewers judgements will be resolved

**Strategy for data synthesis.**

Provide details of the planned synthesis including a rationale for the methods selected. This must be

specific to your review and describe how the proposed analysis will be applied to your data.

 **Analysis of subgroups or subsets.**

* State any planned investigation of ‘subgroups’. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.
* Planned ‘subgroup’ analysis or investigation of potential effect modifiers in reported in systematic review protocols should include:
	+ The rationale for the investigation (why are differences anticipated, or why is it important to look separately at
	+ different types of study or individual)
	+ Clear definitions of which types of study or individual will be included in each group (e.g. study design such as randomised/ non-randomised trial, intervention type such as high dose/low dose drug, setting such as hospital/home care, participant characteristics such as male/female, stage III/stage IV tumour, <18 years/ ≥18 years)
	+ Details of the planned analytic approach (e.g. meta-regression, tests of interaction between groups, logistic regression using individual-level data). Where applicable this should include details of statistical models to be used.

**Dissemination plans.**

* Give brief details of plans for communicating essential messages from the review to the appropriate audiences.
* Any knowledge transfer or implementation activities beyond publication of the final report that are planned should be included.

**Have you checked the PROSPERO database and other databases to identify if this review is being undertaken / has been undertaken?**

If yes, what was the date of the check?

If not – you must complete this.

**Will you be registering your protocol with PROSPERO , or OSF or other method of pre-registration of the study?**

# Proposal for study using secondary data (quantitative).

This form must be accompanied by a Data Management Plan and Ethics Application (for secondary data analysis).

This form is adapted from the Secondary data Pre-registration form available of the OSF <https://osf.io/x4gzt/?view_only=>

Examples of how to complete some questions can be viewed at the OSF website.

**Study Title**

**Research Questions**

List each research question included in this study.

**Hypotheses.**

 For each of the research questions listed above, provide one or more specific and testable hypothesis. Please make clear whether the hypotheses are directional (e.g., A > B) or non-directional (e.g., A ≠ B). If directional, state the direction. You should also refer to your proposal and other evidence to provide a rationale for each hypothesis. \*( see OSF for examples of brief rationales)

**Data description**

1. Name and briefly describe the dataset(s), and if applicable, the subsets of the data you plan to use.
2. Include the type of data (e.g., cross-sectional or longitudinal), the general content of the questions, and some details about the respondents. In the case of longitudinal data, information about the survey’s waves is useful as well.
3. Specify how you will have access to the data.
4. Data Collection Procedures: If the data collection procedure is well documented, provide a link to that information. If the data collection procedure is not well documented, describe, to the best of your ability, how data were collected.
5. Describe the representativeness of the sample and any possible biases stemming from the data collection.
6. Codebook availability: If a codebook is publicly available, link, cite, or upload the document. If not, provide other available documentation.

**Variable**s

1. Manipulated Variables (if applicable)

If you are going to use any manipulated variables from the study variables, identify them here. Describe the variables and the levels or treatment arms of each variable. Note that this is not applicable for observational studies and meta-analyses. If you are collapsing groups across variables this should be explicitly stated, including the relevant formula. If your further analysis is contingent on a manipulation check, describe your decisions rules here.

1. Measured Variables

Describe both outcome measures as well as predictors and covariates and label them accordingly.

If you are using a scale or an index, state the construct the scale/index represents, which items the scale/index will consist of, and how these items will be aggregated.

If you are using any categorical variables, state how you will code them in the statistical analyses.

1. Unit of Analysis

Which units of analysis (respondents, cases, etc.) will be included or excluded in your study? Taking these inclusion and exclusion criteria into account, indicate the expected sample size of the data you’ll be using for your statistical analyses. If you have a research question about a certain group you may need to exclude participants based on one or more characteristics.

1. Missing Data

What do you know about missing data in the dataset (i.e., overall missingness rate, information about differential dropout)? How will you deal with incomplete or missing data? Provide descriptive information, if available, on the amount of missing data for each variable you will use in the statistical analyses.

1. Sampling Weights

Are there sampling weights available with this dataset? If so, are you using them or are you using your own sampling weights? Sampling weights can be useful in secondary data analysis because the sample may not be entirely representative of the population you are interested in.

If you do not seek to make any claims that are generalizable to the national population you may not need to include sampling weights.

**Analyses**

1. Statistical Models

For each hypothesis, indicate the proposed statistical model you will use to test the hypothesis. Include the type of model (e.g., ANOVA, multiple regression, SEM)

Present the statistical power available to detect the predicted effect size or the smallest effect size of interest.

# Proposal for study using secondary data (qualitative).

This form must be accompanied by a Data Management Plan and Ethics Application (for secondary data analysis).

This form is adapted from the Secondary data Pre-registration form available of the OSF <https://osf.io/x4gzt/?view_only=>

**Study Title:**

**Research Questions**

List each research question that will be addressed by this study.

1. **Data description**
	1. Name and briefly describe the dataset(s), and if applicable, the subsets of the data you plan to use.
	2. Include the type of data (e.g., interview, focus group) and the general content.
	3. Specify how you will have access to the data.
	4. Data Collection Procedures: Provide an overview of the original data collection procedure.
	5. Briefly describe the participants.
2. **Analysis**
	1. Briefly describe the analysis plan, and process. Indicate what method and approach you will take.
	2. Describe and/or link to any previous analysis of this data, indicating how your planned analysis differs from what has been done already.
3. **Consent**
	1. Describe the process of consent for the original data collection and a copy of the original ethics approval.
	2. Provide a copy of the original consent form, indicating where it allows for re-analysis of the data as proposed for your research.