Template for writing observational Study Protocol for PhD Degree

General instructions:

1-The protocol should be written in “Times new Roman” Font 12, with normal page layout margins, justified paragraph style and line spacing of 1.15. Titles should be written in Bold, “Times new Roman” Font 14 and subtitles in Bold “Times new Roman” Font 12.

2-Each section of the protocol (Introduction, Aim, Methods,…) should start in a separate page.

3-The page numbering of the protocol should be at the bottom centre of each page.

4-Title page and protocol checklist should not be numbered.

5- The candidate should add the page number of each item in the checklist.

6- The reviewer checks each item in the checklist and writes ✓ if the item is fulfilled.

7- Words in blue are to be replaced by the relevant data.

**Title (Intervention/exposure versus control/placebo for achieving an outcome in a certain population: A case control study/cohort study/ cross sectional study)**

**Arabic Title: An Arabic translation of the English title**

Protocol submitted to

Faculty of Dentistry, Cairo University

for partial fulfilment of the requirements for the PhD Degree in ………..

**By**

**(Name, Affiliation, degrees and year of graduation)**

**2018**

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| Code: | |
| Supervisors’ signature | Head of department’s signature |
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| Protocol Checklist | | | | |
| **Section and topic** | Item  No. | Checked item | Reported on page NO. | Reviewer’s check |
| **I. Administrative information** |  | | | |
|  | 1 | Title: PECOS elements included |  |  |
| 2 | Protocol registration |  |  |
| 3 | Protocol version |  |  |
| 4 | Funding |  |  |
| 5 | Roles and responsibilities of the authors |  |  |
|  | | | | |
| **II. Introduction** | | | | |
|  | 6a | Scientific background |  |  |
|  | 6b | Review of literature |  |  |
|  | 6c | Specific objectives |  |  |
|  | | | | |
| **III. Methods** | | | | |
| **A) Study design and settings** | 7 | Study design |  |  |
| 8 | Settings |  |  |
| **B) Participants** | 9a | Eligibility criteria |  |  |
| 9b | Methods of selection or case/control ascertainment |  |  |
| 9c | Methods of follow up for cohort studies and rationale for choosing cases and controls for case control studies |  |  |
| 10 | *Matched cohort study*—matching criteria and allocation ratio (exposed: non-exposed)  *Matched case-control study*— matching criteria and allocation ratio (case: control) |  |  |
| **C) Variables** | 11 | Clearly define all variables including outcomes and exposures |  |  |
| 12 | For each variable of interest, give data sources/ measurement |  |  |
| 13 | Addressing potential sources of bias |  |  |
| **D) Study size** | 14 | Study size |  |  |
| **E) Quantitative** **variables** | 15 | Handling of quantitative variables in the analyses |  |  |
| **F) Statistical** **methods** | 16a | Statistical methods used to control for confounders |  |  |
| 16b | Subgroup analyses |  |  |
| 16c | Management of missing data |  |  |
| 16d | *Cohort study*—If applicable, management of attrition bias  *Case-control study*—If applicable, statistical method of matching  *Cross-sectional study*—If applicable, analytical methods for different sampling strategies |  |  |
| 16e | Sensitivity analyses |  |  |
| **IV- Ethics and dissemination** | 17a | Research ethics approval |  |  |
| 17b | Protocol amendments |  |  |
| 17c | Informed Consent |  |  |
| 17d | Confidentiality |  |  |
| 17e | Declaration of interests |  |  |
| 17f | Access to data |  |  |
| 17g | Dissemination policy |  |  |
|  | | | | |
| **V- Appendix** | 18 | Informed consent |  |  |
| **VI- Statement of originality** | 19 | Statement of originality |  |  |
|  | | | | |
| **VII- References** |  | References by reference manager |  |  |
|  | | | | |
| **Evidence based committee (Reviewers)** | | | | |
| **Name** | | **Signature** | **Date** | |
| **1.** | |  |  | |
| **2.** | |  |  | |
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| **Research plan committee** | | | | |
| **Name** | | **Signature** | **Date** | |
| **1.** | |  |  | |
| **2.** | |  |  | |

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| **I. Administrative information:**  **1. Title:**  (Intervention/exposure versus control/placebo for achieving an outcome in a certain population: A case control/ cohort/ cross-sectional study). Elements of PECOS should be included in the title. Try to make the title as concise as possible by reducing the words like evaluation, effect, comparison etc. Study design is an essential part of the title.  **2. Protocol registration**  Site and registration number of the protocol should be reported before final approval of the protocol (e.g. Clinicaltrials.gov: NCT01066572).  **3. Protocol version:**  Date and version identifier. (e.g. 25 Jul 2018 Protocol. version number: 5)  **4. Funding:**  Information on potential relationships between researchers and sponsors should be made clearly available to readers, to provide sufficient information on potential conflicts of interest.  **5. Roles and responsibilities:**  a- Name  Affiliation (e.g. Professor….), roles (e.g. Supervisor) and responsibilities in the study (e.g. responsible for data management or data collection).  b- Name  Affiliation, roles and responsibilities in the study  c- Name  Affiliation, roles and responsibilities in the study  **II. Introduction:**  6a. In this section state the research question(s), prevalence of the outcome and its potential association with an exposure that justifies the conduction of the study. You have to rationalize elements of PECO/PEO in this section, while referencing your sentences using a reference manager.  6b. Review of literature: Review briefly the existing body of knowledge on the topic. This section should be backed up by a brief and focused literature review of previous related studies highlighting inadequacies in the body of evidence.  6c. The section should include the objective(s) and hypotheses (null and/or alternative).  **III. Methods:**  **A) Study design and setting**  **7. Study design**  Present key elements of study design early in the protocol describing the group of persons that comprised the study and their exposure/diseased status.  **8. Settings**  Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.  **B) Participants**  **9. Eligibility criteria and selection methods**  For each study design consider reporting the following  (a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  (b) 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  (c) Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants  **10. Matching criteria and allocation ratio**  For each study design consider reporting the following  (a) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed  (b) Case-control study—For matched studies, give matching criteria and the number of controls per case  **C) Variables**  **11. Details about variables**  Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.  **12. Data sources and management**  For each variable of interest, give sources of data and details of methods of assessment (measurement). Separate information for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies, should be given. Describe comparability of assessment methods if there is more than one group.  **Example:**  ‘‘Total caffeine intake was calculated primarily using US Department of Agriculture food composition sources. In these calculations, it was assumed that the content of caffeine was 137 mg per cup of coffee, 47 mg per cup of tea, 46 mg per can or bottle of cola beverage, and 7 mg per serving of chocolate candy. This method of measuring (caffeine) intake was shown to be valid in both the NHS I cohort and a similar cohort study of male health professionals (...) Self-reported diagnosis of hypertension was found to be reliable in the NHS I cohort’’  **13. Addressing potential sources of bias**  Describe any efforts to address potential sources of bias.  **D) Study size**  **14. Study size**  Explain how the study size is calculated. The importance of sample size determination in observational studies depends on the context.  A study should be large enough to obtain a point estimate with a sufficiently narrow confidence interval to meaningfully answer a research question. Large samples are needed to distinguish a small association from no association. Small studies often provide valuable information, but wide confidence intervals may indicate that they contribute less to current knowledge in comparison with studies providing estimates with narrower confidence intervals.  **E) Quantitative variables**  **15. Handling of quantitative variables in the analyses**  Explain how quantitative variables are handled in the analyses. If applicable, describe which groupings are chosen and why. Investigators make choices regarding how to collect and analyse quantitative data about exposures, effect modifiers and confounders. For example, they may group a continuous exposure variable to create a new categorical variable.  **F) Statistical methods**  **16. Statistical methods**  16a. Describe all statistical methods, including those used to control for confounding  16b. Describe any methods used to examine subgroups and interactions  16c. Explain how missing data are addressed  16d. For the following designs explain  - Cohort study—If applicable, explain how loss to follow-up is addressed  - Case-control study—If applicable, explain how matching of cases and controls is addressed  - Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy  16e Describe any sensitivity analyses  **IV. Ethics and dissemination:**  **17a. Research ethics approval**  Plans for seeking research ethics committee/institutional review board (REC/IRB) approval  **17b. Protocol amendments**  Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, analyses)  **17c. Informed consent**  Who will obtain informed consent or assent from potential trial participants.  **17d. Confidentiality**  How personal information about enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial.  **17e. Declaration of interest**  Financial and other competing interests for principal investigators for the overall trial and each study site  **17f. Access to data**  Statement of who will have access to the final trial dataset.  **17g. Dissemination policy**  -Plans for investigators to communicate trial results to participants, healthcare professionals, the public, groups (e.g., via publication), including any publication restrictions.  -Authorship eligibility guidelines and any intended use of professional writers  -Plans, if any, for granting public access to the full protocol & participant dataset.  **V. Appendices**  **18. Informed consent**  Model consent form and other related documentation given to participants.  **VI- Statement of originality:**  Research point should be novel such as a new intervention, new assessment method, ……… Highlight the originality of your research point. Describe how your research is innovative and original. Explain how it adds to existing literature in your field. e.g. will it extend an area of knowledge, be applied to new contexts, solve a problem, test a theory, or challenge an existing one?  **VII- References:**  All references should be written in the same font, and should be written through a citation/reference manager e.g. Mendeley or endnote. All references should follow the same style (author date style or cite-right Harvard is preferred). |