Template for writing in vitro Study Protocol for Master 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 center 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.

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| Title (Intervention/exposure versus control/placebo for achieving an outcome in a certain population: A (non-) /randomized in vitro study)**Arabic Title: An Arabic translation of the English title**Protocol submitted to Faculty of Dentistry, Cairo Universityfor partial fulfillment of the requirements for the Master Degree in ……….. **By****(Name, Affiliation, degrees and year of graduation)****2018**

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| Code:  |
| Supervisors’ signature | Head of department’s signature |
| 1- |  |
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| Date |  |
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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 |  |  |
| 2 | Protocol registeration |  |  |
| 3 | Protocol version |  |  |
| 4 | Funding |  |  |
| 5 | Roles and responsibilities |  |  |
|  |
| **II. Introduction** |
|  | 6a  | Scientific background |  |  |
| 6b | Review of literature |  |  |
| 6c  | Specific objectives  |  |  |
|  |
| **III. Methods** |
| **A) Samples, intervention and outcomes** | 7  | Calculated sample size  |  |  |
| 8  | Description of samples  |  |  |
| 9 | The intervention for each group  |  |  |
| 10  |  Outcomes |  |  |
| **B) Assignment to intervention** |  | If randomized report the following: |
|  | 11  | Sequence generation |  |  |
| 12  | Allocation concealment mechanism |  |  |
| 13  | Implementation |  |  |
| **C) Blinding** | 14  | Blinding |  |  |
| **D) Statistical methods**  | 15  | Statistical methods for comparisons of groups |  |  |
|  |
| **IV- Ethics** | 16 |  Research ethics approval |  |  |
|  |
| **V- References** |    |
|  |
| **Evidence based committee (Reviewers)** |
| **Name** | **Signature** | **Date** |
| **1.** |  |  |
| **2.** |  |  |
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| **Research plan committee** |
| **Name** | **Signature** | **Date** |
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| **I. Administrative information:****1. Title:**(Intervention/exposure versus control/placebo for achieving an outcome in a certain population: An in vitro study). Elements of PICO 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 <https://www.nature.com/protocolexchange/> and registration number of the protocol should be reported before final approval of the protocol **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:**1- NameAffiliation (e.g. Professor….), roles (e.g. Supervisor) and responsibilities in the study (e.g. responsible for sequence generation allocation concealment, randomization and data management).2- NameAffiliation, roles and responsibilities in the study 3- NameAffiliation, roles and responsibilities in the study **II. Introduction:** 6a. In this section state the research question and the problem of the control that made you search for a new intervention to replace it. You have to rationalize elements of PICO 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 (but not in details). Review previous related studies highlighting inadequacies in the body of evidence6c. The section should clarify the objective(s) and hypotheses (null and/or alternative).**III. Methods****A) Samples, intervention and outcomes****7. Calculated sample size**Detailed reporting of the calculation of sample size is a requirement for good comprehension of the methodology used. It is essential to tell the sample size that is sufficient to find statistically significant differences between the groups.**8. Description of study sample**If applicable provide a list for the eligibility criteria of the included sample. This might not apply to all in vitro studies, hence reporting of eligibility criteria is an option that is used whenever applicable. Describe in details how the samples were prepared to receive the required interventions.**9. Intervention for each group** The intervention for each group should be reported with sufficient details, including how and when it was administered to enable replication. Who was involved in the intervention should be also reported.**10. Outcomes** Completely defined, pre-specified primary and secondary measures of outcome, including how and when they will be assessed should be clearly stated. Method of and unit of measurements should be also clearly identified in a table. The following is an example for a table of outcomes.

|  |  |  |  |
| --- | --- | --- | --- |
| **Prioritization of Outcome** | **Outcome** | **Method of Measurement** | **Unit of Measurement** |
| Primary outcome | Fracture resistance | Universal testing machine | Newton |

 **B) Assignment to intervention**Items 11, 12 and 13 are reported if randomization is applicable. **11. Sequence generation**Mechanism used to implement the random allocation sequence (for example, sequentially numbered containers). **12. Allocation concealment** Describe any steps taken to conceal the sequence until intervention is assigned (for example opaque sealed envelopes). **13. Implementation**Details about who generate the random allocation sequence, who enrolls specimens or teeth and who assigns them to intervention, are also important to ensure concealment of allocation.**C) Blinding****14. Blinding**If possible, who is blinded after assignment to intervention (for example, those assessing outcomes), and what is the method of blinding.**D) Statistical methods** 15. Statistical methods used to compare groups for primary and secondary outcomes. Information should be concisely reported, but in sufficient detail to enable understanding of the statistical approach by other researchers or interested readers.**IV- Ethics:**16. Research ethics approval**V- 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). |