

Instruction for Protocol Writing

1. Please fill in all the included sections and don't delete any part of the template
2. For choice brackets, please just use the fill in function in word
3. Type by **Times New Roman, size 14**
4. **The title** and Supervisor names by **Bold font**
5. **References** should be according to Vancouver' style, listed in text by first name as **(El Taieb et al., 2024)** and alphabetically in the reference list
6. **Background:** (Describe the research question and justification for undertaking the study explaining the aspects of novelty in the study)
7. **Objectives:** (describe specific objectives or hypotheses behind the study)
8. **Study design:** (Please fill in the appropriate study design, see attached PDF guide)
9. **Population of study:** (Please provide all details regarding participants including gender, age range and disease conditions. Also indicate if this protocol involves children, prisoners, pregnant women or cognitively impaired or mentally disabled subjects)
10. **Study location:** (Please provide where the study will be conducted and from where study participants will be recruited)
11. **Potential risks:** (Please mention all risks involved even mild ones as pain, discomfort, chance of infection or psychological effects)
12. **Confidentiality of data:** (Please explain how privacy and confidentiality of data and records will be maintained)

13.Primary outcomes (Most important measurable outcomes)

14.Secondary outcome parameters (other outcomes to be assessed)

15.Sample size (number of study subjects included and justification including the clinical and statistical assumptions supporting sample size calculation)

16.Statistical analysis (Please describe your data analysis plan)

17.Source of funding: (Please include source of funding even if self funding)

18.The Arabic summary: just summarize your proposal in Arabic not to translate the total protocol, just 1-2 pages.