

Dental Research Administration Study Design Checklist

Survey Study

This checklist is based on the guidelines for research at the Tufts University School of Dental Medicine. By following the checklist, researchers can develop their studies more efficiently. Please note that this is not necessarily comprehensive, and some items might not apply to your specific study, since every study is unique. It is important that you think about all of the unique aspects of a potential study before commencing with your research.

Initial Project Development

- ☐ The research question is well-defined
- ☐ A specific hypothesis has been developed
- ☐ Relevant literature has been reviewed
- ☐ Dental Research Administration has been contacted to discuss the research process

Subjects / Groups

- ☐ The research question can be answered with the chosen study population / groups
- ☐ Appropriate inclusion / exclusion rules have been developed
- ☐ The inclusion of an appropriate control group has been considered
- ☐ The subject population is accessible
- ☐ Subject recruitment and payments (if applicable) have been reviewed and approved by Dental Research Administration and the department chair

Variables

- ☐ The factors under study (independent variables) and outcomes have been defined
- ☐ All variables that are needed to answer the research question will be collected
- ☐ All variables that are needed to describe the study population, such as demographics, will be collected
- ☐ No unnecessary data will be collected
- ☐ The scale / units have been defined for every variable

Further Elements of Study Design

- ☐ A pilot study has been considered (if the purpose of the study is to determine feasibility of a larger study)
- ☐ The methodology is adequate to ensure accurate measurement of all variables
- ☐ Potential sources of bias, including all variables that could influence the results, have been identified and controlled when possible
- ☐ It has been determined whether the survey has been previously validated, and if not a plan of how validity and/or reliability testing will be done has been developed
- ☐ Other limitations of the study, and their effects on the study's potential conclusions, have been identified and minimized

- ☐ A statistician has approved the sample size, sampling plan, randomization plan, data analysis plan, and data formatting plan

Logistical Concerns

- ☐ A realistic, acceptable timeline has been developed
- ☐ A realistic, acceptable budget has been developed and approved
- ☐ All team members are aware of their roles and are prepared for the study, including being current with required trainings
- ☐ A data and safety management plan has been defined to protect / organize collected data and any necessary contracts have been administered by Dental Research Administration
- ☐ Compensation for survey participation has been considered and a plan for compensation has been developed if applicable
- ☐ A source of funding has been identified, if applicable
- ☐ A plan for how the survey will be distributed (e.g., paper or electronic) has been developed in accordance with human subjects protections concerns
- ☐ The amount of identifiable information to be collected on the survey has been minimized, and the identifiers to be collected have been clearly outlined
- ☐ If a coding mechanism will be used to de-identify the data, a plan of how the code will be created, where the link between the identifiable and de-identified data will be kept, and if/when the link will be destroyed has been made
- ☐ An explanation of why the study is being done (so that a participant may understand the study) and how long it will take for a participant to complete the survey has been written
- ☐ A plan for obtaining consent from subjects has been developed (e.g., information sheet, informed consent form)
- ☐ If sensitive questions are included (e.g., questions concerning use of illegal drugs, alcohol, pregnancy, STIs, etc.), a justification of the questions is included as well as plans to protect confidentiality and provide counseling, if applicable

Protocol

- ☐ The research importance is justified in the protocol
- ☐ The protocol is well-written and is free of grammatical / typographical errors
- ☐ The protocol includes all required sections
- ☐ The protocol includes enough detail for the study to be reproduced by an independent researcher
- ☐ The protocol has been finalized and the study Principal Investigator (PI) has approved the final version

Institutional Review Board (IRB) Considerations (no study activities may begin until after IRB approval)

- ☐ A research coordinator has been contacted to assist with developing supporting paperwork (e.g., consent forms, advertising, recruitment materials, etc.)
- ☐ All paperwork has been prepared by the coordinator and reviewed and approved by the study team
- ☐ The PI has signed the IRB paperwork
- ☐ All paperwork has been approved by Dental Research Administration