

Dental Research Administration Study Design Checklist

Clinical 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. These items are for developing a clinical study at TUSDM; for official reporting guidelines, see the CONSORT Statement at <http://www.consort-statement.org/>.

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)
- Blinding procedures are in place as appropriate
- Plans for calibration / measurement of intra- and inter-rater reliability are in place as appropriate
- 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
- 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
- Clinic space has been scheduled with the appropriate coordinator(s) and/or investigator(s)
- It has been determined whether the device, drug, or product is investigational and/or whether it is being used as FDA approved, if applicable
- Compensation for participation has been considered and a plan for compensation has been developed if applicable
- A source of funding has been identified, if applicable
- Subject safety has been considered with all risks and benefits detailed
- All procedures have been outlined as either standard of care at TUSDM or for the research study only
- A plan for obtaining informed consent from subjects has been developed
- A plan for product accountability (e.g., storage, tracking) has been developed if applicable
- A plan for advertising and recruitment of subjects has been developed

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