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

Dental Research Administration Study Design Checklist

Bench / Laboratory 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.

All bench / laboratory studies, regardless of whether they involve human subject materials, must be submitted to Dental Research Administration for review.

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

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 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
- ☐ Laboratory / bench space has been scheduled with the appropriate technician(s) and/or investigator(s)
- ☐ 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
- ☐ A plan detailing all needed supplies has been developed
- ☐ A source of funding has been identified, if applicable
- ☐ If extracted teeth are being collected, a plan for where they will be collected from (including a letter attesting to the deidentification of the teeth written by the donor and/or Principal Investigator [PI]) and what solution they will be stored in 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 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
- ☐ 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

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

Dental Research Administration Study Design Checklist

Record Review 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 information (e.g., records) is accessible

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
- A source of funding has been identified, if applicable
- 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
- A plan for where the charts are coming from (e.g., TUSDM axiUm, Tufts Medical Center, outside practice, TUSDM academic records) has been developed
- What data to be collected from the records, including any identifiable information if applicable, has been clearly defined
- If a coding mechanism will be used to de-identify the collected 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
- The date range the records will be from has been defined (the dates must all be in the past)
- The maximum number of records to be reviewed has been determined
- If an axiUm query will be done, the study team has met with IT and search codes or key words have been determined
- If student academic records will be reviewed, the study team has met with the appropriate office (e.g., Academic Affairs, Student Affairs) to determine if they can provide the information

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
- 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

Dental Research Administration Study Design Checklist

Qualitative Interview and/or Focus Group 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 study aim(s) are well-defined including the overarching goal(s) / question(s)
- ☐ Relevant literature has been reviewed / environmental scan has been completed
- ☐ Dental Research Administration has been contacted to discuss the research process

Subjects / Groups

- ☐ The study aims can be achieved with the chosen study population / groups
- ☐ Appropriate inclusion / exclusion rules have been developed
- ☐ 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 and outcomes have been defined
- ☐ All variables that are needed to describe the study population, such as demographics, will be collected if necessary

Further Elements of Study Design

- ☐ Deidentification and recording procedures are in place as appropriate
- ☐ The methodology is adequate to ensure best data collection practices
- ☐ Potential sources of bias have been identified and minimized
- ☐ Other limitations of the study, and their effects on the study's potential conclusions, have been identified and minimized
- ☐ Interview and/or moderator guides have been designed and written using the appropriate communication / behavioral theories and questions are written at the appropriate comprehension level

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
- ☐ A script for the interview / focus group has been developed for each audience group
- ☐ An explanation of why the study is being done (so that a participant may understand the study) and how long the interview / focus group will last has been written
- ☐ Logistics have been considered – where the interview / focus group will occur, who will moderate, who will facilitate
- ☐ Compensation for interview / focus group 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 recording / transcribing the interview / focus group data has been developed
- ☐ 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