

University of Puerto Rico • Medical Sciences Campus Human Research Subjects Protection Office (HRSPO)



SUGGESTED OUTLINE FOR RESEARCH PROPOSAL

INVESTIGATORS AND INSTITUTION OF AFFILIATION

All investigators must be in the study.

STUDY TITLE

The title should be the same in all the documents including in the submission.

RESEARCH QUESTION

What is the research question?

HYPOTHESIS & SPECIFIC AIM

What is the hypothesis? How will this hypothesis be tested? Describe the specific aims.

BACKGROUND/SIGNIFICANCE

Why is the question important? How will the answer advance our knowledge?

LITERATURE REVIEW

Previous researches.

METHODOLOGY AND STUDY DESIGN

What type of study will be used? Why was this design chosen?

STUDY SUBJECTS

How will subjects be recruited/selected? Will a sampling strategy be used? What criteria must subjects satisfy to be included? Will any subjects be excluded? How will ensure human subjects protections?

VARIABLES

What are the key outcome and predictor variables? How will they be defined and measured? What confounding variables will be considered if any?

ANALYTIC PLAN

How will the data be analyzed (general approach only)?

LIMITATIONS

What are the limitations of the study that may affect its validity and/or generalizability?

REFERENCES