

# Suggested Outline of a Proposal for an Intramural Research Study

## Investigators

All investigators must be in the study.

## Title

Provide a short descriptive title. The title should be the same in all the documents including in the system.

## Research Question

What is the research question?

## Hypothesis & Specific Aim

What is the hypothesis? How will this hypothesis be tested?

## Background/Significance

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

## 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?  
(Inclusion and Exclusion criteria)

## 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