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