Title of project:

- Hypothesis
  - What is the null hypothesis

- Purpose
  - What is the relevance of the study AND the existing literature

- Methods
  - Study design
    - Retrospective
      - Case series, case-control, cohort, cross-sectional
    - Prospective
      - Experimental, cohort
  - What are the data, variables that will be employed
    - Type of data: categorical, continuous, ordinal
    - What are the dependent & independent variables
    - What are potential confounding variables and sources of bias
  - Outcome(s) of interest
    - How will this be measured
  - Power calculation
    - Sample size
    - Effect size (outcome of interest) based on prior pilot data or published data
    - Level of statistical significance AND clinical relevance (significance)

- Administrative
  - Division under which research is conducted
    - PI – faculty member
    - All other individuals involved
  - Funding
    - Potential source of funding and funding cycle
  - Regulation
    - Are there any conflicts of interest or ethical concerns
    - IRB submission
    - Study oversight and compliance
  - Feasibility
    - Is the study realistically accomplished
      - Is there enough time? Adequate resources? Enough subjects to power?

- End Objective
  - Target meeting AND journal

This project has been discussed in detail according to this outline between faculty and resident.

______________________________________________  ____________________________  ____________________________  ____________________________
Signature (faculty)  Date  Signature (resident)  Date