

Minimal Risk Protocol Template: (usually ends up about 3-6 pages)

A. Introduction

Background/history of disease/condition that is being studied.

B. Rationale/Purpose of Study

Reason that this study is being proposed, and how the results may impact the treatment of the disease/condition.

C. Objectives

Goals which are empirically measurable.

D. Hypothesis

Tentative assumption made to test and/or explain the anticipated data.

E. Study Design

Should detail how the study will be performed including each study visit and what will happen during each visit. Give the dates ranges for accessed PHI (if applicable). Need to include all the data points that will be obtained. Also need to give subject selection criteria in inclusion/exclusion format.

If project will have multiple components or phases identify each.

F. Financial Implications

Will there be any costs to the subjects? If yes, list the charges and description of why.

G. Stats justification for number of patients

Give detail as to how the number of subjects was chosen. What number will give you statistical viability or make your results meaningful?

H. Risks/Safety

Mention level of risk associated with study, efforts to minimize risk, how confidentiality will be protected, and if there are any advantages or disadvantages to alternative procedures for the subject.

Identify consenting process (or if requesting a waiver of consent)

I. Potential Benefits

Elicit any positive outcomes for the patient or society in general.

J. Stats Methods and Data Analysis

Mention sample size, simple overview of potential statistical tests and math that

might be employed for analysis, techniques for efficacy analysis if needed. Detail what comparisons will be made with the data categories.

K. Study Conduct and Compliance

Determine that study will be conducted in accordance with Dept of Health and Human Services and/or FDA regulations or Good Clinical Practice (if applicable). Who will conduct the trial and who is responsible for data gathering, management, analysis etc.