



PROTOCOL SYNOPSIS

TITLE	
SPONSOR NAME & QUALIFICATIONS	
NATURE OF REQUEST (e.g., Study Drug, Funding Only, Drug and Funding)	
NUMBER OF SITES	
RATIONALE	
STUDY DESIGN	
PRIMARY OBJECTIVE	
SECONDARY OBJECTIVES	
TERTIARY OBJECTIVE	
SETTING	
NUMBER OF SUBJECTS	
SUBJECT SELECTION CRITERIA	



PRODUCT, DOSE, AND ROUTE OF ADMINISTRATION	
CONTROL PRODUCT, DOSE AND ROUTE OF ADMINISTRATION	
DURATION OF SUBJECT PARTICIPATION AND DURATION OF STUDY	
CONCOMITANT MEDICATIONS	
STUDY EVALUATIONS	
SAFETY EVALUATIONS	
PLANNED INTERIM ANALYSES	
STATISTICS PRIMARY ANALYSIS PLAN	
RATIONALE FOR NUMBER OF SUBJECTS	