PROTOCOL SYNOPSIS TEMPLATE

The shared research proposal remains the intellectual property of the CIRSE member. The information will be held in confidence by Next Research and will not be used for any purpose without prior approval.

TITLE	
PHASE	
STUDY DESIGN Summarize the study design, including type of study, number of arms, controls or comparators	
INDICATION/TARGET POPULATION	
INTERVENTION(S) & INVESTIGATIONAL PRODUCT(S)	
RATIONALE	
OBJECTIVES	Primary objective Secondary objectives Exploratory objectives
PRIMARY ENDPOINT(S) Describe the Primary Endpoint(s) and the set of measurements used to address the objectives	
SECONDARY & EXPLORATORY ENDPOINTS Describe the Secondary & Exploratory Endpoint(s) and measures that will address them	
NUMBER OF PATIENTS	

Provide the total number of study subjects, the number per study arm, and justification	
NUMBER OF SITES Given the desired number of patients and estimated annual patient numbers, how many sites need to be included at a minimum?	
DURATION OF STUDY AND FOLLOW-UP PERIOD Specify the length of the patient inclusion and follow-up periods	
INCLUSION/EXCLUSION CRITERIA	
SAFETY CONSIDERATIONS What adverse events are expected? How will adverse events be collected and according to which criteria?	
STATISTICAL CONSIDERATIONS	