<TITLE>

The title should be easy to remember, recognizable by administrative support staff, and sufficiently different from other protocol titles to avoid confusion. Brevity with specificity and neutrality is the goal. If there is a "short title" (e.g., an abbreviation used to refer to the study title, include here and that can be used throughout this document in place of the full title).

Protocol Number: < Number>

National Clinical Trial (NCT) Identified Number: <Number, if available>

Principal Investigator: < Principal investigator>

<IND/IDE> Sponsor: <Sponsor name, if applicable>

Sponsor means an individual or pharmaceutical or medical device company, governmental agency, academic institution, private organization, or other organization who takes responsibility for and initiates a clinical investigation.

Funded by: < NIH Institute or Center (IC)>

Version Number: v.<x.x>

<Day Month Year>

All versions should have a version number and a date. Use the international date format (day month year) and write out the month (e.g., 23 June 2015).

SYNOPSIS

Title:	<Full title>
Study Description:	*Provide a short description of the protocol, including a brief statement of the study hypothesis. This should be only a few sentences in length. A detailed schematic describing all visits and a schedule of assessments should be included in the* ***Schema and Schedule of Activities, Sections 1.2 and 1.3,*** *respectively.*
Objectives:	*Include the primary and secondary objectives. These objectives should be the same as the objectives contained in the body of the protocol. These align with Primary Purpose in clinicaltrials.gov*[1]*.* <Primary Objective: Secondary Objectives: >
Endpoints:	*Include the primary endpoint and secondary endpoints. These endpoints should be the same as the endpoints contained in the body of the protocol. These align with Outcome Measures in clinicaltrials.gov.* <Primary Endpoint: Secondary Endpoints: >
Study Population:	*Specify the sample size, gender, age, demographic group, general health status, and geographic location.*
Phase:	<2 or 3 or N/A> *Phase applies to drugs and biologics.*
Description of Sites/Facilities Enrolling Participants:	*Provide a brief description of planned facilities/participating sites enrolling participants. Indicate general number (quantity) of sites only and if the study is intended to include sites outside of the United States.*
Description of Study Intervention:	*Describe the study intervention. If the study intervention is a drug or biologic, include dose and route of administration. For devices, provide a description of each important component, ingredient, property and the principle of operation of the device.*
Study Duration:	*Estimated time (in months) from when the study opens to enrollment until completion of data analyses.*
Participant Duration:	*Time (e.g., in months) it will take for each individual participant to complete all participant visits.*