

## **Protocol Title**

## **Investigator(s)**

## **Version Date**

### **Objectives:**

*Describe the purpose, specific aims, or objectives of the research. State the hypotheses to be tested. Include primary and secondary objectives if appropriate.*

### **Background:**

*Provide the scientific or scholarly background and rationale for the research based on the existing literature (include references). Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Explain the significance of the research in terms of why it's important and how it will add to existing knowledge. Describe the importance of the knowledge expected to result.*

### **Setting of the Research:**

*Describe the setting and location in which the research will be conducted.*

### **Resources Available to Conduct this Research:**

*Demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period or access to the estimated number of charts needed to review. Describe the time that you will devote to conduct and complete the trial within the agreed trial period (i.e. 10% of PI's time; full time coordinator). Describe the number and qualifications of your staff and their experience in conducting research. Describe your facilities. Describe the process/plan to ensure that all research investigators/staff assisting in this trial are adequately informed of the protocol, revisions to the protocol, study specific changes, investigational product information, and study related duties and functions.*

### **Study Design:**

#### Recruitment Methods

*Describe when, where, and how potential subjects will be recruited. If a chart review, describe how and which records will be accessed to collect data. Describe the source of subjects. Describe the methods that will be used to identify potential subjects. Describe materials, such as advertisements, that will be used to recruit subjects (include these with submission materials). Describe the amount and timing of any payments to subjects. Describe the total expected number of subjects needed to complete the research.*

#### Inclusion and Exclusion Criteria

*Describe how you will screen for eligibility. Describe the criteria that define who will be included or excluded in your final study sample. Describe the expected number of subjects needed to complete the research. If a chart review, include the dates between which you will collect data (i.e. Subjects who had XX procedure between 6/1/00 and 6/1/05).*

*Indicate specifically whether you will include or exclude each of the following special populations:*

*Adults unable to consent*

*Individuals who are not yet adults (infants, children, teenagers)*

*Pregnant women*

*Prisoners*

*(You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)*

### Study Endpoints

*Describe the primary and secondary study endpoints. Describe any primary or secondary safety endpoints.*

### Procedures Involved in the Research

*Describe and explain the study design (i.e. randomized, double-blind, placebo-controlled, retrospective chart review). Provide a timeline of all procedures being performed, including procedures being performed to monitor subjects for safety or minimize risks. Identify procedures being performed already for diagnostic or treatment purposes and differentiate between these and the procedures performed solely for the research. Describe and justify the route of administration, dosage, dosage regimen, and treatment period(s). Provide the overall duration of the research. Describe the procedures taken to lessen the probability or magnitude of risks. Describe the source records that will be used to collect data about subjects.*

### Data Management

*Describe the data and specimens to be sent out or received. Describe what information will be included in that data or associated with the specimens. Describe who is responsible for receipt or transmission of the data. Describe how specimens and data will be transported. Describe the plan to manage the data. Describe any procedures that will be used for quality control of collected data. Describe the data analysis plan, including any statistical procedures. Provide a power analysis.*

### Provisions to Monitor the Data for the Safety of Subjects

*Delete this section if your research involves **no more than minimal risk** to subjects. Describe the plans to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. Describe who will review the data. Describe what data are reviewed, including safety data, untoward events, and efficacy data. Describe when data are reviewed.*

### Withdrawal of Subjects

*Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent. Describe any procedures for orderly termination. Describe procedures that will be followed when subjects withdraw from the research (or request that their data be withdrawn), including partial withdrawal from procedures with continued data collection.*

*If based on the design of the study, there is no possibility of withdrawal of subjects, state that in this section*

## **Statistical Plan**

### Sample Size Determination

*Describe the statistical methods for determining the sample size for the study (reason for choice of sample size).*

### Statistical Methods

*Describe the statistical methods to be employed, including timing of any planned interim analysis(es); the level of significance to be used; criteria for termination; Procedures for accounting for missing, unused, and spurious data; Procedures for reporting any deviation(s) from the original statistical plan should be described and justified in the protocol and/or in the final report, as appropriate. The selection of subjects to be included in the analysis (e.g., all randomized subjects, all dosed subjects, all eligible subjects, evaluate-able subjects).*

### **Risks to Subjects**

*List the risks, discomforts, hazards or inconveniences to the subjects. For each indicate the probability, magnitude, and duration. Consider physical, psychological, social, legal and economic risks. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.*

### **Potential Benefits to Subjects**

*Describe the benefits that individual subjects may experience. For each indicate the probability, magnitude, and duration of the benefit. Indicate if there is no direct benefit.*

### **Provisions to Protect the Privacy Interests of Subjects**

*Describe the steps that will be taken to protect subjects' privacy interests. "privacy interest" refers to a person's desire to control access of others to themselves. Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.*

### **Provisions to Maintain the Confidentiality of Data**

*Describe the steps that will be taken to abide by promises made to the subject to limit dissemination of identifiable data. Describe where data will be stored, who will have access to the data, measures taken to secure the data (i.e. password protected), and how long data will be stored.*

### **Medical Care and Compensation for Injury**

*Delete this section if your research involves **no more than minimal risk** to subjects. Describe the provisions for medical care and available compensation in the event of research related injury.*

### **Cost to Subjects**

*Describe any costs that subjects may incur through participation in the research.*

### **Incentives/Payments to Subjects**

*Describe any incentives for subjects to participate in the research.*

### **Consent Process**

*Describe the setting of the consent process. Describe the role of the individuals involved in the consent process and the time that will be devoted to the consent discussion. Describe any waiting period between informing the prospective subject and obtaining the consent. Describe any steps that will be taken to minimize the possibility of coercion or undue influence.*

*If the research involves a **waiver or alteration of the consent process** (consent will not be obtained, required information will not be disclosed, or the research involves deception) describe.*

*If the research involves **children** describe how consent will be conducted. Describe whether parental permission will be obtained from either both parents or just one parent. Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.*

*If the research involves **adults who may be unable to consent**, describe the process to determine whether an individual is capable of consent. If permission of a LAR will be obtained list the individuals from whom permission will be obtained. Describe the process for assent of the subjects. Indicate whether assent will be required of all, some, or none of the subjects. If some, indicated which subjects will be required to assent and which will not. If assent will not be obtained from some or all subjects, an explanation of why not. Describe whether assent of the subjects will be documented and the process to document assent.*

### **Vulnerable Populations**

*For each vulnerable population that will be participating in the study, describe the scientific rationale for including them and the additional safeguards to protect their rights and welfare. Ensure that any vulnerable populations are listed in your inclusion criteria.*

### **Sharing of Results with Subjects**

*Describe if any research results will be shared with subjects. If so, describe what results will be shared, how this information will be communicated to subjects, and circumstances when results will be shared. Indicate whether the study will be placed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov)*

### **References**

*Cite the references relevant to this Protocol.*