**SUNY DOWNSTATE MEDICAL CENTER**

**RESEARCH PROTOCOL**

# Protocol Title

# Version

# Principal Investigator

# Introduction/Background Information

## Aims & Objectives

## Hypotheses

# Methods

## Overview of the Study Design

## Study Population

### Inclusion and Exclusion Criteria

### Sample Size

### Method for Screening For Eligibility

### Inclusion of Vulnerable Populations

## Statistical Considerations

### Analysis PlaN

### Sample Size Justification

# Procedures and Data Collection

## Follow-Up

## Duration of Study

# Human Research Considerations

## Recruitment Procedures

## Risks/Discomforts

## Potential Benefits

## Informed Consent

## Confidentiality

## Data and Safety Monitoring

## Discontinuation of Research Participants/Withdrawal

## Record Retention

## Conflict of Interest

## Reportable Events

As required by Policy IRB-01, all reportable events will be reported to the IRB within the specified deadlines. Additional information is provided in the IRB Guidance on “Reportable Events.” Events are defined in the IRB Guidance on “Acronyms and Definitions.” For additional information see: <http://research.downstate.edu/irb/irb-policies.html>

# Additional Information

# Appendices

# References/Biography