**Study Protocol**

**Study Title:**

**Principle Investigator:**

**Co-Investigators:**

**Study Sites:**

**Background and Significance**

**Hypothesis**

**Aims**

**Study Design and Methodology**

**Inclusion Criteria**

**Exclusion Criteria**

**Potential benefits to subjects and/or society:**

**Potential risks to subjects and precautions taken to minimise risk:**

**Study Duration/ Study Timeline:**

**Informed Consent Process:**

**Data Safety Monitoring:**

**Conflict of Interest:**