**Study Population Characteristics**

* 1. **Conditions or Focus of Study**

**1.2 Eligibility Criteria**

**1.3 Age Limits**

Minimum Age

Maximum Age

**1.4 Inclusion of Women, Minorities, and Children**

**1.5 Recruitment and Retention Plan**

**1.6 Recruitment Status**

**Response:**

**1.7 Study Timeline**

**1.8 Enrollment of First Subject**

**Response:**

**PROTECTION AND MONITORING PLANS**

**2.1. Protection of Human Subjects:**

**2.2. Is this a Multi-Site Study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?**

 **Yes \_\_\_ No \_\_\_\_ N/A \_\_\_\_**

 **If yes, describe the single IRB plan:**

**2.3 Data and Safety Monitoring Plan:**

**2.4 Will a Data and Safety Board be appointed for this Study?**

**Yes \_\_\_ No \_\_\_\_**

**2.5 Study Team Structure**

**protocol synopsis**

**3.1 Brief Summary**

**3.2 Study Design**

**3.2.a Narrative Study Description**

**3.2.b Primary Purpose**

**Response:**

**3.2.c Intervention**

**Response:**

**3.2.d Study Phase**

**Response:**

**3.2.e Intervention Model**

**Response:**

**3.2.f Masking**

**Response:**

**3.2.g Allocation**

**Response:**

**3.3 Outcome Measures**

**3.4 Statistical Design and Power**

**3.5 Subject Participation Duration**

**3.6 Will the study use an FDA-regulated intervention?**

**Yes \_\_\_ No \_\_\_\_**

**3.7 Dissemination Plan**