STUDY POPULATION CHARACTERISTICS

1.1 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