**ClinicalTrials.gov Database Requirements**

**Observational Study Design Supplemental Questions**

**Study Design**

*Observational Study Model:* [Select one]

Cohort / Case-Control / Case-Only / Case-Crossover / Ecologic or Community / Family Based / Other

*Time Perspective:* [Select one]

Retrospective / Prospective / Cross-Sectional / /Other

*Biospecimen Retention:* [Select one]

None Retained / Samples with DNA / Samples without DNA

*Enrollment:* #\_\_\_ [Select one] Anticipated / Actual

*Number of Groups/Cohorts:* #\_\_\_

**Groups and Interventions**

*Groups*

*Group/Cohort Label:*

Instructions: Brief, descriptive label to be used as row or column heading in tables.

*Group/Cohort Description:*

Instructions: Describe the intervention(s) to be administered. For drugs use generic name and include dosage form, dosage, frequency and duration.

*Add any additional arms by repeating the information above*

*Interventions/Exposures:*

*Intervention Type:* [Select one]

Drug / Device / Biological/Vaccine / Procedure/Surgery / Radiation / Behavioral / Dietary Supplement / / Genetic / Combination Product / Diagnostic Test / Other

*Other Intervention Names (if any):*

Instructions: Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.

*Add any additional intervention names if needed.*

*Intervention Description:*

Instructions: Do not repeat information already included in arm/group descriptions.

*Add any additional intervention names if needed.*

*Cross Reference:*

Instructions: This section is depicted as a matrix within clinicaltrials.gov. Therefore, please list which groups will receive which interventions during this study.