Date Approved: _____

SOF ANCILLARY STUDY PROPOSAL

Ancillary Study Title / Research Question:

Investigator's Name:

Sponsor (if not a SOF investigator):

Investigator's Email:

Other investigators who will be working on this analysis:

Submission deadline for funding (if applicable):

Biospecimen Request:
If you plan to use specimens collected at a SOF visit (includes serum, whole blood, blood blotters, extracted DNA, urine, etc.), please answer the following questions:

Specimen	Number of samples	Type of samples (all, random sample, African American)	Volume/ amount	Visit(s)
Serum				
Whole blood				
Blood blotters				
Urine				
DNA				

1) Briefly describe the measurements to be done and assays to be used:

2) Amount for each assay (eg, 0.5 mL):

3) Total number of assays: (provide information about repeat assays for reliability analyses as well):

4) Can you use previously thawed serum/blood/urine?

5) Are there other constraints for the specimens to be used? (eg, fasting)

Please attach a 5-7 page description of the study that includes the specific aims, short background, and methods. Submit completed form to Dana Robertson at DaRobertson@sfcc-cpmc.net.

- specific aims
- a short background and rationale for the study, including references
- the methods and procedures to be employed

- if data would be collected, a plan for data collection and analysis (including who will be responsible for collecting and analyzing the data)
- the sample size required to answer the research question (including the assumptions underlying these estimates)
- an estimate of the impact of the study on the main trial (e.g. staff and participant time, etc.)
- a proposal for how to approach any IRB/consent issues
- for studies involving biochemical samples: impact of the study on existing biochemical samples, aliquoting, etc. Note: There are limitations on requests for blood for hip fracture and breast cancer cases. If you are requesting use of these specimens, please add a note addressing this point.

Use of SOF Breast Cancer and Hip Fracture Blood Specimens

The following guidelines apply to ancillary study proposals requesting the use of SOF Breast Cancer and Hip Fracture Blood Specimens:

- a SOF PI must serve as a co-sponsor
- proposal must be supported by preliminary results. Proposals for preliminary data will not be approved.
- proposals that only confirm what is already established will not be approved.
- proposals that require ≥ 1 ml will not be approved, unless the study is exceptional and compelling.
- proposals should specify that the technology proposed requires the minimum amount of biospecimens necessary
- proposed studies should have adequate power, but may not use serum from more than half the available breast cancer cases after that collection
  - Proposals should use 2 or 3 non-cases per case to increase power.
- proposals must explain why the cases must include cases with joint outcomes (eg, breast cancer and hip fractures or breast cancer and strokes)
- The SOF Steering Committee will analyze the characteristics of those who had just one outcome and those who had joint outcomes to help determine whether exclusion of cases with 2 outcomes would importantly bias the results.