

January 1, 1998

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Center: _____

Patient Initials: _____, _____
Rand Number: _____Form
completed by: _____**A copy of this form should be faxed to the SCC at (301) 881-5928 by the next working day.****A. VERIFICATION OF INCLUSION CRITERIA** (*all answers must be YES*)

- | | |
|--|-------------------------------|
| 1. Postmenopausal? deleted | Y ₁ N ₃ |
| 2. Qualifying angiogram within previous 4 months? deleted | Y ₁ N ₃ |
| 3. Signed informed consent? deleted | Y ₁ N ₃ |

B. VERIFICATION OF EXCLUSION CRITERIA (*all answers must be NO*)

- | | |
|--|-------------------------------|
| 1. Creatinine >2.0 mg/dL (>177 μmol/L)? deleted | Y ₁ N ₃ |
| 2. Unwilling to stop concurrent hormone replacement therapy? deleted | Y ₁ N ₃ |
| 3. Unwilling to stop vitamin C (>60 mg/day) and/or E (>30 IU/day) supplements?
deleted | Y ₁ N ₃ |
| 4. Planned or prior coronary artery bypass grafting? deleted | Y ₁ N ₃ |
| 5. NYHA class IV heart failure or known ejection fraction <25%? deleted | Y ₁ N ₃ |
| 6. MI less than 4 weeks prior to randomization? deleted | Y ₁ N ₃ |
| 7. Concurrent participation in another blinded clinical trial? deleted | Y ₁ N ₃ |
| 8. Symptomatic gallstones? deleted | Y ₁ N ₃ |
| 9. History of PE or idiopathic DVT? deleted | Y ₁ N ₃ |
| 10. History of hemorrhagic stroke or bleeding diathesis? deleted | Y ₁ N ₃ |
| 11. Breast cancer or mammogram suggestive of cancer? deleted | Y ₁ N ₃ |
| 12. Known endometrial hyperplasia or abnormal uterine bleeding? deleted | Y ₁ N ₃ |
| 13. History of endometrial carcinoma without hysterectomy? deleted | Y ₁ N ₃ |
| 14. Abnormal Pap smear with dysplasia of grade CIN-I or greater? deleted | Y ₁ N ₃ |
| 15. Documented fasting triglycerides >500mg/dL (>5.65 mmol/L)? deleted | Y ₁ N ₃ |
| 16. Uncontrolled diabetes mellitus? deleted | Y ₁ N ₃ |
| 17. Uncontrolled hypertension? deleted | Y ₁ N ₃ |
| 18. Anticipated survival <3 years? deleted | Y ₁ N ₃ |
| 19. Unlikely to adhere to protocol in the opinion of the investigator? deleted | Y ₁ N ₃ |
| 20. Angiogram not meeting protocol criteria? deleted | Y ₁ N ₃ |
| 21. History of osteoporosis, either untreated or currently treated with HRT? deleted | Y ₁ N ₃ |
- ELIG = eligibility criteria satisfied (1=yes; 0=no)**

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C. PHYSICAL MEASURES AT RANDOMIZATION

1. Blood pressure (mmHg): **C_SBP = systolic / C_DBP = diastolic** /
 Systolic Diastolic
2. Height: **C_HCCM** . cm OR ft . in
3. Weight: **C_WTKG** . kg OR lb . oz
4. Waist circumference: **C_WCCM** . cm OR . in
5. Hip circumference: **C_HCCM** . cm OR . in

D. RANDOMIZATION PROCEDURE CHECKLIST

1. Fasting study bloods drawn? **C_FBL** Y1 N3
 a. If Yes, date of samples: **deleted** / /
 Month Day Year
Replaced with C_FBLDY = # of days between randomization and blood draw
2. Study angiogram done? **C_SANG** Y1 N3
 a. If Yes, date of angiogram: **deleted** / /
 Month Day Year
Replaced by C_SANGDY = # of days between randomization and entry angiogram
3. ECG done? **C_ECG** Y1 N3
 a. If Yes, date of ECG: **deleted** / /
 Month Day Year
Replaced by C_ECGDY = # of days between randomization and entry ECG

E. RANDOMIZATION

1. Patient's screening ID number: **deleted**

2. Did the patient have a hysterectomy? **C_HYST**

3. Bottle code of HRT study medication dispensed: **deleted**

Replaced by C_HRTDP =HRT dispensed (0=no; 1=yes)

4. Bottle code of Vitamin C study medication dispensed **deleted**

Replaced by C_VITCDP =Vitamin C dispensed (0=no; 1=yes)

5. Bottle code of Vitamin E study medication dispensed: : **deleted**

Replaced by C_VITEDP =Vitamin E dispensed (0=no; 1=yes)

6. Open label multi-vitamin dispensed? **C_MULTI**

7. Date of randomization: **deleted**

Y₁ N₃

__ - __

C - __

E - __

Y₁ N₃

____ / ____ / ____
Month Day Year