

April 30, 1999

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Center: Patient Initials: Rand Number: Form completed by: **A. VISIT INFORMATION**

1. Visit:  06 6 month  12 12 month  18 18 month  24 24 month  
**G\_VISIT**  30 30 month  36 36 month  42 42 month  99 Non-routine
2. Date of visit: **Recoded as G\_VISDY = days from randomization**  /  /   
 Month Day Year
3. Type of contact: **G\_VISTP**  1 Visit  3 Phone  5 Mail

**B. ADHERENCE** (complete at every visit while participant is on study medication)

1. Number of HRT/HRT placebo pills left: **G\_HRTCNT**
2. Number of Vitamin C/Vitamin C placebo pills left: **G\_CCNT**
3. Number of Vitamin E/Vitamin E placebo pills left: **G\_ECNT**

**C. STUDY DRUG DISPENSATION** (complete for every contact)

1. Bottle code of HRT study medication dispensed: **deleted**
2. Bottle code of Vitamin C study medication dispensed: **deleted**
3. Bottle code of Vitamin E study medication dispensed: **deleted**
4. Open label multivitamin dispensed? **G\_MULTI**  Y<sub>1</sub> N<sub>3</sub>

**D. PHYSICAL MEASURES** (required at 12, 24 and 36 months)

1. Blood pressure (mmHg): **G\_SBP / G\_DBP**  /   
 Systolic Diastolic
2. Height: **G\_HTCM**  .  cm OR  ft  .  in
3. Weight: **G\_WTKG**  .  kg OR  lb  .  oz
4. Waist circumference: **G\_WCCM**  .  cm OR  .  in
5. Hip circumference: **G\_HCCM**  .  cm OR  .  in

**E. PROCEDURES CHECKLIST**

1. Fasting study bloods drawn? (required at 18 and 36 months) **G\_FBL**  Y<sub>1</sub> N<sub>3</sub>
- a. If Yes, date of samples: **Recoded as G\_FBLDY = days since randomization**  /  /   
 Month Day Year
2. ECG done? (required at 12 and 36 months) **G\_ECG**  Y<sub>1</sub> N<sub>3</sub>  
 If Yes, answer questions a. and b. below. If No, continue to section F.
- a. Date of ECG: **Recoded as G\_ECGDY = days since randomization**  /  /   
 Month Day Year
- b. Was atrial fibrillation found on the ECG? **G\_ECGAF**  Y<sub>1</sub> N<sub>3</sub>
- 1) If atrial fibrillation, have oral anticoagulants been prescribed? **G\_ANTICO**  Y<sub>1</sub> N<sub>3</sub>

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Rand Number: \_\_\_\_\_

Form completed by: \_\_\_\_\_

**F. INTERIM MEDICAL HISTORY** (*complete for every contact*)1. **Since the last semi-annual visit**, have you had:a. Coronary angiogram, angioplasty (including stent) or bypass surgery? **G\_CORINT** Y<sub>1</sub> N<sub>3</sub>*If Yes, send all angiograms to the Central Angiography Laboratory*b. Carotid or peripheral vascular angiogram, angioplasty (including stent) or surgery? **G\_CARANG** Y<sub>1</sub> N<sub>3</sub>c. Overnight hospitalization for any reason? **G\_HOSP** Y<sub>1</sub> N<sub>3</sub>d. Bleeding (other than associated with surgery or angioplasty) that required blood transfusion? **G\_BLEED** Y<sub>1</sub> N<sub>3</sub>e. A fracture? **G\_FX** Y<sub>1</sub> N<sub>3</sub>*If necessary, obtain records and complete the Outcomes Form W09.*2. In the past 4 weeks, have you had any chest discomfort? **G\_PAIN4** Y<sub>1</sub> N<sub>3</sub>*If YES, answer a. through e. If NO chest discomfort, go to section G.*a. does this usually occur with exercise, such as walking, climbing stairs, carrying something, or sexual activity? **G\_STAIRS** Y<sub>1</sub> N<sub>3</sub>b. does this usually occur with emotion, such as excitement, stress, tension, or anger? **G\_EMOTE** Y<sub>1</sub> N<sub>3</sub>c. does this awaken you from sleep? **G\_AWAKEN** Y<sub>1</sub> N<sub>3</sub>d. did you have any chest discomfort at rest? **G\_CDREST** Y<sub>1</sub> N<sub>3</sub>e. Choose only one of the following descriptions of the typical level of your discomfort over the past 4 weeks. **G\_LEVEL**

- 1 Ordinary physical activity does not cause angina, or angina only with strenuous or rapid or prolonged exertion.
- 3 Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold may cause angina.
- 5 Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs under normal conditions and at normal pace may cause angina.
- 7 Inability to carry on physical activity without angina or chest pain.

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Please answer all the questions below. If the answer to some questions is unknown, write an asterisk (\*) in the shaded area.

## 1. Lipid Lowering Agents:

a. HMG co-A reductase inhibitor  
**G\_HMG**  Y<sub>1</sub>  N<sub>3</sub>b. Fibric acid derivative?  
**G\_FIBRIC**  Y<sub>1</sub>  N<sub>3</sub>c. Niacin (nicotinic acid)?  
**G\_NIACIN**  Y<sub>1</sub>  N<sub>3</sub>d. Resins? **G\_RESINS**  Y<sub>1</sub>  N<sub>3</sub>e. Others? **G\_OTHLLA**  Y<sub>1</sub>  N<sub>3</sub>

## 2. Diabetes drugs:

a. Insulin? **G\_INSUL**  Y<sub>1</sub>  N<sub>3</sub>b. Oral agents? **G\_POHGLY**  Y<sub>1</sub>  N<sub>3</sub>

## 3. Calcium channel blockers:

a. Dihydropyridine? **G\_DIHY**  Y<sub>1</sub>  N<sub>3</sub>b. Other calcium channel  
blockers?  
**G\_OTHCCB**  Y<sub>1</sub>  N<sub>3</sub>

## 4. Open label medications:

a. Estrogen? **G\_OLHRT**  Y<sub>1</sub>  N<sub>3</sub>b. Vitamin C (other than  
multivitamins)? **G\_OLVITC**  Y<sub>1</sub>  N<sub>3</sub>c. Vitamin E (other than  
multivitamins)? **G\_OLVITE**  Y<sub>1</sub>  N<sub>3</sub>

## 5. Other Current Medications:

a. Digoxin/Lanoxin? **G\_DIG**  Y<sub>1</sub>  N<sub>3</sub>b. Beta blockers? **G\_BETA**  Y<sub>1</sub>  N<sub>3</sub>c. Nitrates, oral or topical?  
(excluding sublingual NTG)  
**G\_NITR**  Y<sub>1</sub>  N<sub>3</sub>d. Aspirin? **G\_ASPRIN**  Y<sub>1</sub>  N<sub>3</sub>e. Other antiplatelet agents?  
**G\_ANTIPL**  Y<sub>1</sub>  N<sub>3</sub>f. Warfarin (coumadin)? **G\_WARF**  Y<sub>1</sub>  N<sub>3</sub>g. Heparin or low molecular weight  
heparin (Enoxaparin)?  
**G\_HEPRIN**  Y<sub>1</sub>  N<sub>3</sub>h. ACE inhibitors? **G\_ACE**  Y<sub>1</sub>  N<sub>3</sub>i. Diuretics? **G\_DIUR**  Y<sub>1</sub>  N<sub>3</sub>j. Blood pressure lowering agents  
(other than calcium channel  
blockers, diuretics, beta  
blockers, or ACE inhibitors)?  
**G\_BPLOW**  Y<sub>1</sub>  N<sub>3</sub>k. Antiarrhythmics? **G\_ANTIAR**  Y<sub>1</sub>  N<sub>3</sub>