

## SECTION 1-A1 PROTOCOL APPENDIX 1

### BASELINE AND FOLLOW-UP VARIABLES

#### 1-A1.1 Variables

**Eligibility Screen (Form 2 or 3)**-- name; mailing address; telephone numbers and best times to call; date of birth; residing in area for next three years; current involvement in other research studies; history of cancer (site, diagnosis in past 10 years); ethnicity; recruitment source; hormone use (present, in last three months); osteoporosis-related fracture and hormone use as treatment; hysterectomy history; last menstrual bleeding; number of meals prepared away from home; special diets (type); history of diabetes, deep vein thrombosis, pulmonary embolus, stroke, transient ischemic attack, myocardial infarction; history of sickle cell anemia, heart failure, liver disease, bleeding problem; loss of 15 pounds in last six months; renal failure requiring hemodialysis; other chronic illness; emotional or mental problems; ability to get to clinical center; interest in DM; interest in HRT (willingness to stop current hormone medications).

**HRT Washout (Form 4)**-- date stopped hormones; assessment of symptoms after stopping (HRT for those on hormones at Initial Contact).

**Final Eligibility Assessment (Form 6)**-- confirmation of eligibility due to medical conditions, depression, substance abuse, staff assessment.

**Initial, HRT, DM, CaD, OS, Consents (Form 11 - Consent Status)**-- date signed or refused; reasons refused; genetic studies consented or refused.

**Personal Information (Form 20)**-- name; address; address and telephone number contacts not living with participant; social security number; education; employment status; occupation; marital status; partner's name, social security number, education, employment status, occupation; total family income; primary health care provider's name, address, phone number; recent history of mammogram, pelvic exam, endometrial aspiration; insurance coverage.

**Personal Information Update (Form 21)**-- name, address, and phone numbers, best time to call; names, addresses, and phone numbers of contacts not living with participant; primary health care provider's name and address.

**Medical History (Form 30)**-- hospitalization history; history of medical conditions; history of heart, circulatory, or coagulation problems; history of arthritis, gallbladder disease, thyroid disease, hypertension, angina, peripheral arterial disease and related procedures, colonoscopy or sigmoidoscopy, stool guaiac; history of cancers (site, age at diagnosis); recent history of falls or syncopal episodes; history of fractures (site, age, number).

**Medical History Update (Form 33)**-- hospitalization since last contact; hospitalization for heart, circulatory, or coagulation problems; stroke or transient ischemic attack, number of falls or syncopal episodes, fractures update; cancer (type, where diagnosed, hospitalization); mammogram; breast biopsy, needle aspiration, or lumpectomy; tests and procedures; electrocardiogram; diagnosis of new conditions; hip or other joint replacement.

**Reproductive History (Form 31)**-- age at menarche; history of menstrual irregularity and amenorrhea; history of menopausal symptoms; history of pregnancy, pregnancy outcomes, infertility; history of breast feeding; history of gynecologic and breast surgeries.

**Family History (Form 32)**-- number of full-blooded sisters and brothers, daughters, and sons; parental age or date of death; relatives' history of diabetes, myocardial infarction, stroke, cancers; fractures in parents (site, age).

**Personal Habits (Form 34)**-- coffee consumption; smoking history; alcohol history; weight change; special diets; history of physical activity and exercise (frequency, duration).

**Personal Habits Update (Form 35)**-- physical activity and exercise; alcohol consumption; current cigarette smoking.

**Thoughts and Feelings/Daily Life (Form 37)**-- social support; social integration; care giving; social strain; optimism; negative emotional expressiveness; hostility; quality of life; symptoms; life events; depression; sleep disturbance; urinary incontinence; sexual functioning.

**Daily Life (Form 38)**-- quality of life; symptoms; life events; depression; sleep disturbance; urinary incontinence; sexual functioning.

**Cognitive Status (Form 39)**-- expanded mini mental status examination.

**Addendum to Medical History Update (Form 40)** -- family history of DVT and PE.

**Addendum to Personal Information (Form 41)**-- racial/ethnic background using 2000 Census questions.

**Hormone Use (Form 43)**-- current and past hormone replacement; history of oral contraceptive, diethylstilbestrol, depo-provera use.

**Current Medications (Form 44)**-- current medication inventory.

**Current Supplements (Form 45)**-- current dietary supplements inventory.

**Estrogen Plus Progestin Survey (Form 49)**-- a list of symptom questions.

**FFQ (Form 60)**-- (145 item Food Frequency Questionnaire)

**Four-Day Food Record (Form 62)**

**24-hour Dietary Recall**

**Physical Measurements (Form 80)**-- blood pressure; resting pulse; height, weight, waist and hip circumference.

**Functional status (Form 90)**-- grip strength; chair stand; time to walk 6 meters.

**Pelvic Exam (Form 81)**

**Pap Smear (Form 92)**

**Endometrial Aspiration (Form 82)**

**Clinical Breast Exam (Form 84)**

**Mammogram (Form 85)**

**ECG (Form 86)**-- Resting 12-lead electrocardiogram.

**Blood collection (Form 100)**-- Hemoglobin, hematocrit, white blood cell count, platelet count, fasting triglycerides (as needed for eligibility at baseline); fasting serum, plasma (citrate and EDTA), buffy coat, RBCs for storage.

#### **Medication Dispensation**

#### **Medication Adherence**

**HRT Safety Interview (Form 10)**-- presence and amount of vaginal bleeding; changes in breasts; presence of other symptoms or worries, health changes that might require stopping study pills, pill-taking behaviors.

**CaD Safety Interview (Form 17)**-- presence of gastrointestinal symptoms or other symptoms or concerns, health changes that might require stopping study pills, pill-taking behaviors.

**HRT Calendar (Form 53)**-- days and amount of vaginal bleeding (HRT women with uterus).

**Observational Study Questionnaire (Form 42)**-- birth weight, birth status, breast feeding at birth; coffee/tea consumption; alcohol history; smoking history; history of breast examination, history of benign breast disease, recent history of mammogram; history of the use of powders in genital area or on sanitary napkins; history of diaphragm; history electric blanket use; religious affiliation; recent history of physical activity and exercise (frequency, duration); occupational history; height and weight history, weight change; state of residence history.

**Observational Study Exposure Update Questionnaires (Example: Form 48)**-- annual updates of key exposure information and assessment of selected new exposures.

**Observational Study Follow-up Questionnaire Year 1 (Form 48)**-- current weight, recent weight change; current food and beverage consumption at meal or snack times, recent use of fats or oils, recent wine consumption; current smoking habits; recent history of hormone replacement; history of insecticide exposure; history of living with pets; history of computer use (frequency, duration); history of hand-held hair dryer use (frequency, duration).

**Observational Study Follow-Up Questionnaire Year 3 (Form 143)**-- recent weight change, figure (weight) identification; current physical activity and exercise (frequency, duration); past strenuous physical activity (frequency); recent use of fats or oils; recent alcohol consumption, change in alcohol consumption habits; recent coffee/tea/water/diet drinks consumption; current smoking, current smoking exposure; current employment status, current marital status, partner's current employment status ; total family income; existence and recent use of usual medical care provider, change in usual medical provider; choice options in current health insurance coverage, type(s) of current health insurance coverage and payment mechanism; recent use of hormone replacement therapy; diagnoses of new medical conditions.

**Observational Study Follow-Up Questionnaire Year 4 (Form 144)**-- current weight, recent weight change; current physical activity and exercise (frequency, duration); exposure and sensitivity to sunlight; current smoking; past and present use of artificial sweeteners; recent use of hormone replacement therapy; diagnoses of new medical conditions; current marital status.

**Observational Study Follow-Up Questionnaire Year 5 (Form 145)**-- current weight, recent weight change, current physical activity and exercise (frequency, duration); current smoking; video; video display terminal exposure; recent emotions; frequency religious practices; recent use of alternative medical treatments; current dental health, frequency of professional dental care; recent use of hormone replacement therapy; diagnoses of new medical conditions; current marital status.

**Observational Study Follow-Up Questionnaire Year 6 (Form 146)**-- current weight, recent weight change, current physical activity and exercise (frequency, duration); current activities; coffee, tea, soft drink, alcohol

consumption; current smoking; smoking exposure; existence and recent use of medical care provider, status and types of health insurance; use of natural hormones; use of osteoporosis prescription medications; recent use of hormone replacement therapy; diagnoses of new medical conditions; current employment status; current marital status; family finances.

**Observational Study Follow-Up Questionnaire Year 7 (Form 147)**— current weight; recent weight change; current physical activity and exercise (frequency, duration); use of weight loss medications; recent use of hormone replacement therapy; diagnoses of new medical conditions; life events; parents birthplace; current marital status.

**Observational Study Follow-Up Questionnaire Year 8 (Form 148)**— current weight; recent weight change; current physical activity and exercise (frequency, duration); current smoking status; use of weight loss medications; coffee, tea, soft drink consumption ; recent use SERMS, recent use of hormone replacement therapy; diagnoses of new medical conditions; family history of senile dementia.

**Bone Density Scan (Form 87)**— (osteoporosis substudy sites only)

**Urine collection (Form 101)**— Urine for storage (osteoporosis substudy sites only).

#### **1-A1.2 Frequency of Collection**

See *Table 1-A1.1* for frequency of data collection.

**Table 1-A1.1**  
**Frequency of Data Collection**

	Screening <sup>1</sup> CT and OS				CT																				OS				
	SV 0	SV 1	SV 2	SV 3	4- 6 wks	6 m	1 Yr	4 wk	6 m	2 Yr	6 m	3 Yr	6 m	4 Yr	6 m	5 Yr	6 m	6 Yr	6 m	7 Yr	6 M	8 Yr	6 m	9 Yr	Close Out	Annual	3 Yr	6 Yr	9 Yr
Eligibility Screen	X			*																									
HRT Washout		X																											
Final Eligibility Assessment		X																											
Initial Consent		X																											
HRT Consent			X																										
DM Consent			X																										
CaD Consent							X																						
Personal Information		X																											
Personal Information Update			*	*	*	*	*		*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	*
Medical History		X																											
Medical History Update						X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Reproductive History			X																										
Family History				X																									
Personal Habits				X																									
Personal Habits Update							X					X						X							X				
Thoughts & Feelings/Daily Life			X																						X				
Daily Life							X					%						%						%			X		
Cognitive Status				%H			%H					%H						%H					%H						
Hormone Use		X																											
Current Medications		X		*			X					X						X						X			X		
Current Supplements		X		*			X					X						X						X			X		
Personal Habits Update							X					X						X						X					
FFQ		X					D			%D		%D		%D		%D		%D		%D		%D		%D			X		
Four-Day Food Record				D			%D																						
24 Hour Dietary Recall				%D			%D			%D		%D		%D		%D		%D		%D		%D		%D					
Physical Measures		X					X			X		X		X		X		X		X		X		X			X	BD	
Waist/Hip Measures		X					X					%						%						%					
Functional Status				%			%					%						%						%					

	Screening <sup>1</sup> CT and OS				CT																				OS				
	SV 0	SV 1	SV 2	SV 3	4- 6 wk s	6 m	1 Yr	4 wk	6 m	2 Yr	6 m	3 Yr	6 m	4 Yr	6 m	5 Yr	6 m	6 Yr	6 m	7 Yr	6 M	8 Yr	6 m	9 Yr	Close Out	Annual	3 Yr	6 Yr	9 Yr
Pelvic (in women with uterus) <sup>2,3</sup>			H				H			H		H		H		H		H		H		H		H					
Pap (in women with cervix) <sup>2,3</sup>			H									H						H							H				
Endometrial Evaluation																													
(in women with uteri) <sup>3</sup>			H									%H						%H						%H					
	Screening <sup>1</sup> CT and OS				CT																				OS				
	SV 0	SV 1	SV 2	SV 3	4- 6 wk s	6 m	1 Yr	4 wk	6 m	2 Yr	6 m	3 Yr	6 m	4 Yr	6 m	5 Yr	6 m	6 Yr	6 m	7 Yr	6 M	8 Yr	6 m	9 Yr	Close Out	Annual	3 Yr	6 Yr	9 Yr
Clinical Breast Exam			HD				H			H		H		H		H		H		H		H		H					
Mammogram			HD				H			X		H		X		H		X		H		X		H	X				
ECG			HD									X						X						X					
Blood Collection		X					X					%						%						%			X		
Medication Dispensation <sup>3,4</sup>			H	H		H	HC			HC		HC		HC		HC		HC		HC		HC		HC					
Medication Adherence				H		H	H		HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	C				
Safety Interview <sup>5</sup>					H	H	H	C	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	C				
HRT Calendar				H		H																							
OS Consent		X																											
OS Questionnaire		X																											
OS Exposure Update <sup>6</sup>																									X				
Bone Densitometry		BD					BD					BD						BD						BD			BD	BD	BD
Urine Collection		BD					BD					BD												BD			BD		BD

**Key**

X = All Participants

D = DM

H = HRT

HC = HRT and CaD

% = Percentage (subsample) of participants

BD = Bone Density sites

\* = "Update"

### Notes

<sup>1</sup> According to screening model, all screening tasks must be completed by SV3.

<sup>2</sup> Pelvic and Pap performed in all HRT women during screening.

<sup>3</sup> These tasks are not required for Estrogen plus Progestin (PERT) participants since study pills were stopped on July 9, 2002.

<sup>4</sup> Clinic option to dispense a six-month supply of study pills semi-annually.

<sup>5</sup> Safety interviews are only required while HRT or CaD participants are taking study pills and for two semi-annual contacts (HRT) or one semi-annual contacts (CaD) after stopping.

<sup>6</sup> OS Exposure Update not done at year 2.





Section 1-A1  
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Baseline and Follow-Up Variables

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