



Form #	Form Name	Screening CT and OS				CT																			OS									
		SV 0	SV 1	SV 2	SV 3	4-6 wk	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	An-nual	3 Yr	6 Yr	9 Yr				
84	Clinical Breast Exam			HD			H			H		H		H		H		H		H		H		H		H								
85	Mammogram			HD			H			X		H		X		H		X		H		X		H		H								
86	ECG			HD								X						X					X											
87	Bone Density		BD				BD					BD												BD	BD		BD	BD	BD					
90	Functional Status				%HD		%					%					BD	%					%											
92	Pap			H								H						H					H											
100	Blood Collection		X				X					%											%				X							
101	Urine Collection		BD				BD					BD					%						BD			BD		BD		BD				
143	OS Follow-up (Year 3)																																	
144	OS Follow-up (Year 4) <sup>1</sup>																										X							
145	OS Follow-up (Year 5) <sup>1</sup>																																	
146	OS Follow-up (Year 6)																																	
147	OS Follow-up (Year 7) <sup>1</sup>																																	
148	OS Follow-up (Year 8) <sup>1</sup>																																	
149	Supplement to OS Follow-up <sup>1</sup>																																	

<sup>1</sup> See description in Baseline and Follow-up Variables table for timing of data collection.

**Key:** X = All Participants

D = DM

H = HRT

C = CaD

O = OS

% = Percentage (subsample) of participants

BD = Bone Density sites

## Baseline and Follow-Up Variables

Form and variables	Timing and Subsample Notes (See table above for frequency of collection)
<p><b>Form 2 - Eligibility Screen</b> -- 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).</p>	<p>Updated at final screening contact.</p>
<p><b>Form 4 - HRT Washout</b> -- date stopped hormones; assessment of symptoms after stopping (HT for those on hormones at initial contact).</p>	
<p><b>Form 10 - HRT Management and Safety Interview</b> -- presence and amount of vaginal bleeding; changes in breasts; currently taking medications, or have symptoms, worries, or health changes that might require stopping study pills; pill-taking behaviors.</p>	<p>Required semi-annually and at non-routine contracts initiated by participant while HRT participants were taking study pills, and for two semi-annual contacts after stopping study pills.</p>
<p><b>Form 17 - CaD Management and Safety Interview</b> -- presence of gastrointestinal symptoms, currently taking medications, or have symptoms, concerns, or health changes that might require stopping study pills; pill-taking behaviors.</p>	<p>Required semi-annually and at non-routine contracts initiated by participant while CaD participants were taking study pills, and for one semi-annual contact after stopping study pills.</p>
<p><b>Form 20 - Personal Information</b> --education; employment status; occupation; marital status; partner's education, employment status, occupation; total family income; recent history of mammogram, pelvic exam, endometrial aspiration; insurance coverage; serve in armed services.</p>	
<p><b>Form 25 – Participant Treatment Assignment: Estrogen plus Progesterone/E-Alone</b> – date stopped study pills; symptoms when stopped; guess on treatment assignment and reasons.</p>	<p>For E+P, when intervention stopped July 9, 2002. For E-Alone, when intervention stopped in February 2004.</p>
<p><b>Form 28 – Participant Treatment Assignment CaD</b> -- when stopped study pills, guess on treatment assignment and reasons.</p>	<p>At CaD study close-out October 2004-March 2005.</p>
<p><b>Form 30 - Medical History Questionnaire</b> -- 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).</p>	

Form and variables	Timing and Subsample Notes (See table above for frequency of collection)
<b>Form 31 - Reproductive History</b> -- 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.	
<b>Form 32 - Family History Questionnaire</b> -- 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).	
<b>Form 33 - Medical History Update</b> -- 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.	
<b>Form 34 - Personal Habits Questionnaire</b> -- coffee consumption; smoking history; alcohol history; weight change; special diets; history of physical activity and exercise (frequency, duration).	
<b>Form 35 - Personal Habits Update</b> —physical activity and exercise; alcohol consumption; current cigarette smoking.	
<b>Form 37 - Thoughts and Feelings</b> -- social support; social integration; care giving; social strain; optimism; negative emotional expressiveness; hostility; Form 38 – Daily Life items: quality of life; symptoms; life events; depression; sleep disturbance; urinary incontinence; sexual functioning.	
<b>Form 38 - Daily Life</b> -- quality of life; symptoms; life events; depression; sleep disturbance; urinary incontinence; sexual functioning.	6% CT cohort subsample (8.6% HT and 4.3% DM; same as Form 80 [for hip/waist] and Form 100-Blood cohort).
<b>Form 39 - Cognitive Assessment</b> -- expanded mini mental status examination.	HT cohort aged 65 and over.
<b>Form 40 - Addendum to Medical History Update</b> -- family history of DVT and PE. (2002)	Initiated in 2002 and collected once from all CT and OS participants at next routine contact.
<b>Form 41 - Addendum to Personal Information</b> -- racial/ethnic background using 2000 Census questions. (2002)	Initiated in 2002 and collected once from all CT and OS participants at next routine contact.
<b>Form 42 - Observational Study Questionnaire</b> -- 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.	
<b>Form 43 - Hormone Use Interview</b> – current and past hormone replacement (duration, frequency); history of oral contraceptive, diethylstilbestrol, depo-provera use.	

Form and variables	Timing and Subsample Notes (See table above for frequency of collection)
<b>Form 44 – Current Medications</b> –current medication name, form, strength, duration.	
<b>Form 45 – Current Supplements</b> –current supplement name; vitamin and mineral type, dose, frequency, duration.	
<b>Form 48 – OS Follow-up Questionnaire (Year 1)</b> -- 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).	
<b>Form 49 - Estrogen Plus Progestin Survey</b> – date stopped; take hormones since stopped and reasons; take hormones now; current symptoms and severity; how manage symptoms; depression scale; sexual functioning; current medications, natural hormones; quality of life.	For E+P participants on study through July 8, 2002, when intervention was; administration began in March 2003.
<b>Form 55 - Estrogen-Alone Survey</b> – current symptoms; how manage symptoms; sexual functioning; current medications, natural hormones; take hormones since stopped and reasons; take hormones or SERMS now.	For all E-Alone participants; administered twice: first in Jan. 2004 before the intervention was stopped on February 28, 2004, and again at close-out visit.
<b>Form 60 – Food Questionnaire</b> -- 145 item Food Frequency Questionnaire.	Year 2: 30% cross sectional; Year 3,6: 4.3% cohort (same as blood subsample) and 5.7% repeated cross-sectional; Year 4,5,7: 10% cross-sectional. In 2000 implemented subsample so each DM participant received a FFQ at least once every 3 years.
<b>Form 80 - Physical Measurements</b> – resting pulse and blood pressure; height, weight; waist and hip circumference.	Waist and hip measurements at Year 3,6, and 9 in 6% CT cohort subsample (8.6% HT and 4.3% DM; same as Form 38-Daily Life and Form 100-Blood cohort). For BD sites, height at OS Year 6.
<b>Form 81 - Pelvic Exam</b> – physical exam results; presence of cystocele, rectocele; uterine presence, size, prolapse; adnexae; follow-up results.	Not required for E+P participants after July 9, 2002, when intervention was stopped.
<b>Form 82 - Endometrial Aspiration</b> – uterine depth; aspiration results; follow-up results.	5% E+P participants with uterus at indicated contacts, and at other contacts to manage unexpected bleeding. Not required after July 9, 2002, when intervention was stopped.
<b>Form 83 – Transvaginal Uterine Ultrasound</b> – endometrial thickness; pathology results; endometrial cavity fluid; follow-up results.	Done only if endometrial aspiration could not be done or was refused.

Form and variables	Timing and Subsample Notes (See table above for frequency of collection)
<b>Form 84 - Clinical Breast Exam</b> – nipple discharge; skin, axillary, or breast mass; mass size, mobility, number; follow-up results.	Optional for DM participants.
<b>Form 85 - Mammogram</b> -- summary results, follow-up results.	
<b>Form 86 – ECG</b> – 12 lead ECG	
<b>Form 87 – Bone Density Scan</b> – hip, spine, and whole body scan	Collected only at 3 Bone Density sites; not required on enhanced recruitment participants at these sites. Collected at close-out if did not reach Year 9.
<b>Form 90 - Functional Status</b> -- grip strength; chair stand; 6 meter timed walk.	25% CT cohort aged 65 and over.
<b>Form 92 - Pap Smear</b> -- type cells present; pathology results; follow-up results.	HT women with cervix.
<b>Form 100 - Blood Collection and Processing</b> -- hematocrit, white blood cell count, platelet count, fasting triglycerides (for HT participants if serum lipemic); fasting serum, plasma (citrate and EDTA), buffy coat, RBCs for storage; time since ate; physical exercise and aspirin use before blood drawn; time drawn, centrifuged, removed from cells, frozen.	6% CT cohort subsample (8.6% HT and 4.3% DM; same as Form 38-Daily Life and Form 80 [for hip/waist] cohort). Hct, platelet count, WBC done only at screening on CT and OS participants; triglyceride done on HT participants if serum lipemic.
<b>Form 101 - Urine collection and Processing</b> – first morning void urine for storage; time collected, centrifuged, removed to vials, frozen.	Collected only at 3 Bone Density sites; not required on enhanced recruitment participants.
<b>Form 143 - OS Follow-Up Questionnaire (Year 3)</b> -- recent weight change, figure (weight) identification; current physical activity and exercise (frequency, duration); usual activities; past strenuous physical activity by age (frequency); recent alcohol consumption, change in alcohol consumption habits; recent coffee/tea/water/diet drinks consumption; recent use of fats or oils; 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.	OS Follow-Up Questionnaire not done at Year 2.
<b>Form 144 - OS Follow-Up Questionnaire (Year 4)</b> -- 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.	
<b>Form 145 – OS Follow-Up Questionnaire (Year 5)</b> -- current weight, recent weight change; current physical activity and exercise (frequency, duration); current smoking; video, video display terminal exposure; depression scale; 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.	
<b>Form and variables</b>	<b>Timing and Subsample Notes</b> (See table above for frequency of collection)
<b>Form 146 – OS Follow-Up Questionnaire (Year 6)</b> -- current weight, recent weight change; current physical activity and exercise (frequency, duration); usual 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; family history of Alzheimer's; current employment status; current marital status; family finances.	
<b>Form 147 – OS Follow-Up Questionnaire (Year 7)</b> -- 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; family history of breast cancer; life events; parents' birthplace; current marital status.	
<b>Form 148 – OS Follow-Up Questionnaire (Year 8)</b> -- 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; current marital status.	
<b>Form 149 – Supplement to OS Follow-Up Questionnaire (Year 9)</b> -- care giving responsibilities; life events; breast cancer; use of weight loss medications; parents' birthplace.	For OS participants who did not reach Year 7 by time of closeout.

Data Collection Schedule for Extension Studies											
Form #	Data collection	Extension Study 2005-2010					Extension 2010-2015				
		2005-6	2006-7	2007-8	2008-9	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
--	Re-consent and Personal Information Update	X					X				
33	Medical History Update	X	X	X	X	X	X	X	X	X	X
150	Hormone Use Update	HT	HT	HT	HT	HT					
85	Mammogram	HT	HT								
134	Addendum to Medical History Update	X									
151	Activities of Daily Life (ADL)	X	X	X	X	X	X		X	X	X
155	Lifestyle Questionnaire (includes ADL)							X			
153	Medication and Supplement Inventory				X				MRC		
154	Breast Health Supplement to the Medication Inventory				B						
	24-Hour Recall		%DM			%DM					
	Long Life (home visit) data collection							HV	HV		
X = all Extension participants											
HT = Previous Hormone Trial participants											
MRC = Previous Hormone Trial participants and all African American and Hispanic participants											
B = all participants who previously reported diagnosis of breast cancer											
% DM = 4.6% of Dietary Modification Trial participants, with half in first part											
HV = All participants who consented to the Home Visit (18 month period)											