

AD \_\_\_\_\_

Award Number: DAMD17-01-1-0124

TITLE: Selenium and Breast Cancer Chemoprevention

PRINCIPAL INVESTIGATOR: Henry J. Thompson, Ph.D.

CONTRACTING ORGANIZATION: AMC Cancer Research Center  
Lakewood, Colorado 80214

REPORT DATE: August 2002

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20030317 007

# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

|  |   |  |  |  |
|--|---|--|--|--|
| 1. AGENCY USE ONLY (Leave blank)   |   | 2. REPORT DATE<br>August 2002                              | 3. REPORT TYPE AND DATES COVERED<br>Annual (1 Aug 01 -31 Jul 02) |  |
| 4. TITLE AND SUBTITLE<br>Selenium and Breast Cancer Chemoprevention  |   |  | 5. FUNDING NUMBERS<br>DAMD17-01-1-0124                           |  |
| 6. AUTHOR(S)<br>Henry J. Thompson, Ph.D.   |   |  |  |  |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)<br>AMC Cancer Research Center<br>Lakewood, Colorado 80214<br><br>E-MAIL:<br><a href="mailto:thompsonh@amc.org">thompsonh@amc.org</a>  |   |  | 8. PERFORMING ORGANIZATION<br>REPORT NUMBER                      |  |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)<br>U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Maryland 21702-5012  |   |  | 10. SPONSORING / MONITORING<br>AGENCY REPORT NUMBER              |  |
| 11. SUPPLEMENTARY NOTES  |   |  |  |  |
| 12a. DISTRIBUTION / AVAILABILITY STATEMENT<br>Approved for Public Release; Distribution Unlimited  |   |  | 12b. DISTRIBUTION CODE   |  |
| 13. ABSTRACT ( <i>Maximum 200 Words</i> )<br>The primary objective of this project is to determine whether selenium supplementation affects candidate markers of breast cancer risk in a cohort of women at elevated risk for breast cancer. The intermediate biomarkers to be studied are: indicators of oxidative damage to cellular macromolecules such as DNA and lipid, indicators of IGF metabolic status, and cellular indicators of breast cancer risk. We propose a randomized, placebo-controlled, double-blind chemoprevention trial with 150 participants (75 subjects per arm) using a placebo tablet or a tablet containing 200 µg high-selenium brewer's yeast per day, given for a duration of one year. The form and dose of selenium that will be used has been reported to reduce cancer incidence and mortality in lung, prostate, and colon. Blood and urine will be collected at baseline, and after 6 and 12 months of intervention. The feasibility of obtaining breast epithelial cells via nipple aspiration at baseline and the end of the intervention is being assessed. Plasma selenium and glutathione peroxidase activity will be evaluated in addition to pill counts and self report as markers of compliance. |   |  |  |  |
| 14. SUBJECT TERMS:<br>breast cancer, prevention, chemoprevention, Selenium, oxidative damage, IGF-1  |   |  | 15. NUMBER OF PAGES<br>47  |  |
|  |   |  | 16. PRICE CODE   |  |
| 17. SECURITY CLASSIFICATION<br>OF REPORT<br>Unclassified   | 18. SECURITY CLASSIFICATION<br>OF THIS PAGE<br>Unclassified | 19. SECURITY CLASSIFICATION<br>OF ABSTRACT<br>Unclassified | 20. LIMITATION OF ABSTRACT<br>Unlimited                          |  |

## Table of Contents

|  |             |
|--|-------------|
| <b>Cover.....</b>                        | <b>1</b>    |
| <b>SF 298.....</b>                       | <b>2</b>    |
| <b>Table of Contents.....</b>            | <b>3</b>    |
| <b>Introduction.....</b>                 | <b>4</b>    |
| <b>Body.....</b>                         | <b>4</b>    |
| <b>Key Research Accomplishments.....</b> | <b>5</b>    |
| <b>Reportable Outcomes.....</b>          | <b>5</b>    |
| <b>Conclusions.....</b>                  | <b>5</b>    |
| <b>References.....</b>                   | <b>5-6</b>  |
| <b>Appendices.....</b>                   | <b>7-47</b> |

## **Introduction**

The primary objective of this project is to determine whether selenium supplementation affects candidate markers for breast cancer risk in a cohort of women at elevated risk for breast cancer. The intermediate biomarkers being studied are: indicators of oxidative damage to cellular macromolecules such as DNA and lipid, indicators of IGF metabolic status, and cellular indicators of breast cancer risk.

## **Body of Report**

### **Approved Statement of Work**

We are conducting a randomized, placebo-controlled, double-blind chemoprevention trial with 150 participants (75 subjects per arm) using a placebo tablet or a tablet containing 200 µg high-selenium brewer's yeast per day, given for a duration of one year. Blood and urine are being collected at baseline, and after 6 and 12 months of intervention. Efforts are being made to obtain breast epithelial and/or breast fluid via nipple aspiration using a modified breast pump. This procedure is performed at baseline and the end of the intervention. Randomization will be in 15 blocks of 10 subjects each.

#### **1. Year 01**

- a. Final development of project materials including Web-based randomization program, data entry screens, data quality assurance procedures, project databases.
- b. Obtain all supplements.
- c. Initiate recruitment and enter 3 blocks of 10 subjects.
- d. Schedule follow-up visits.
- e. Institute monthly patient follow-up.
- f. Ongoing collection and analyses of biological samples.
- g. Enter results into databases.
- h. Submit progress report.

#### **2. Years 02-03**

- a. Enter remaining subjects into the study and continue follow up, sample collection and analyses. Goal is 8 blocks of 10 in year 02 and 4 blocks of 10 in year 03.
- b. Submit progress reports.

#### **3. Year 04**

- a. Complete follow up and the collection and analysis of all samples.
- b. Evaluate all data.
- c. Summarize findings for publication and submit final report.

**Acronym for Study** We refer to this project as the **ENRICH** study.

### **Progress on Year 01 Objectives**

- a. Final development of project materials including Web-based randomization program, data entry screens, data quality assurance procedures, project databases.**

This objective has been accomplished. We decided to develop a laptop computer based randomization process with daily backup to an FTP site that is monitored by the Data Coordinating Center staff. An extensive array of project materials were developed, reviewed and approved by the local and DOD IRB, and are in use. These materials are included in the appendix.

- b. Obtain all supplements.**

Placebo and selenium tablets were obtained from Cypress Systems Inc., Fresno, CA. The multi-vitamin and mineral supplement has the same formulation as being used in the NCI-sponsored SELECT trial and was obtained from BioAdventex Pharma, Wilmington, DE.

**c. Initiate recruitment and enter 3 blocks of 10 subjects.**

During this reporting period, recruitment was initiated and 27 individuals have been enrolled in the project.

**d. Schedule follow-up visits.** Follow-up visits are scheduled at the time of the baseline clinical visit. To date, this system is working effectively.

**e. Institute monthly patient follow-up.** Monthly calls are being placed to each individual participating in the project. These calls are made by the project's clinical coordinator. The project nurse project follows-up if additional medical input is required. To date, this approach to compliance and safety monitoring has been well-received by participants and is working effectively.

**f. Ongoing collection and analyses of biological samples.** Upon collection, samples are immediately processed by the clinical coordinator. All samples are rapidly frozen when processing is completed, and are logged into the project database. Samples are evaluated per assay protocols.

**g. Enter results into databases.** As clinical and laboratory data are collected, they are entered into the project database. Hand entered data is either double-entered for validation or is 100% site-verified.

**h. Submit progress report.** This document.

**Key Research Accomplishments** All project materials (paper and electronic) required to initiate recruitment were completed during this reporting period, and enrollment in the project was initiated. Because of the double-blind study design, no biological data is currently available.

**Reportable Outcomes (cumulative)**

- Supporting intervention materials were developed and tested (when appropriate).
- The project database was completed
- Participants are being enrolled

**Potential Obstacles** The project's Nurse Practitioner was sent to both Fox Chase Cancer Center in Philadelphia, PA and the Breast Center at the University of Kansas which is directed by Dr. Carol Fabian for training in obtaining nipple aspirate fluid (NAF). To date, our success in obtaining adequate NAF samples is limited. To address this potential problem, two alternatives are being pursued. The PI has contacted staff at the Breast Center at UCSF in order to obtain additional training for the nurse practitioner. Also, the PI is establishing contacts with NCI collaborators to determine the feasibility of performing serum and/or nipple aspirate fluid-based proteomic analyses using SELDI-TOF as an alternative to cell-based risk assessment using NAF.

**Conclusions** Work is progressing as planned, and alternative approaches to cell-based risk assessment using NAF are being explored.

**References (cumulative)**

1. Clark, L.C., Combs, G.F., Jr., Turnbull, B.W., Slate, E.H., Chalker, D.K., Chow, J., Davis, L.S., Glover, R.A., Graham, G.F., Gross, E.G., Kronrad, A., Leshner, J.L., Jr., Park, H.K., Sanders, B.B., Jr., Smith, C.L., and Taylor, J.R. (1996) Effects of selenium supplementation for cancer prevention in patients with carcinoma of the skin. A randomized controlled trial. Nutritional Prevention of Cancer Study Group [see comments] [published erratum appears in JAMA 1997 May 21;277(19):1520]. *JAMA*, 276, 1957-1963.

2. Clark,L.C., Combs,G.F., Jr., Turnbull,B.W., Slate,E.H., Chalker,D.K., Chow,J., Davis,L.S., Glover,R.A., Graham,G.F., Gross,E.G., Krongrad,A., Leshner,J.L., Jr., Park,H.K., Sanders,B.B., Jr., Smith,C.L., and Taylor,J.R. (1996) Effects of selenium supplementation for cancer prevention in patients with carcinoma of the skin. A randomized controlled trial. Nutritional Prevention of Cancer Study Group. *JAMA*, **276**, 1957-1963.
3. Clark,L.C., Dalkin,B., Krongrad,A., Combs,G.F., Jr., Turnbull,B.W., Slate,E.H., Witherington,R., Herlong,J.H., Janosko,E., Carpenter,D., Borosso,C., Falk,S., and Rounder,J. (1998) Decreased incidence of prostate cancer with selenium supplementation: results of a double-blind cancer prevention trial. *Br.J.Urol.*, **81**, 730-734.
4. Clark,L.C. and Marshall,J.R. (2001) Randomized, controlled chemoprevention trials in populations at very high risk for prostate cancer: Elevated prostate-specific antigen and high-grade prostatic intraepithelial neoplasia. *Urology*, **57**, 185-187.
5. Combs,G.F., Jr., Clark,L.C., and Turnbull,B.W. (1997) Reduction of cancer mortality and incidence by selenium supplementation. *Med.Klin.*, **92 Suppl 3**, 42-45.
6. Combs,G.F., Jr., Clark,L.C., and Turnbull,B.W. (1997) Reduction of cancer risk with an oral supplement of selenium. *Biomed.Enviro.Sci.*, **10**, 227-234.
7. Nelson,M.A., Porterfield,B.W., Jacobs,E.T., and Clark,L.C. (1999) Selenium and prostate cancer prevention. *Semin.Urol.Oncol.*, **17**, 91-96.

# Appendices



1600 Pierce Street • Denver, Colorado 80214 • www.amc.org

CENTER FOR NUTRITION IN THE PREVENTION OF DISEASE



## Information Sheet

### Selenium and Breast Cancer Chemoprevention

#### Enrich Project

#### 12-month study

##### Purpose of study

The purpose of this study is to determine whether selenium, taken as a tablet causes changes in early indicators of breast cancer risk. The study is being conducted in a group of women at increased risk for breast cancer. Past research indicates that the amount and type of selenium can reduce deaths due to cancer of the lung, prostate, and colon. However, the effects of selenium on breast cancer have not been studied. That is the purpose of this project.

The change from a normal breast cell into breast cancer takes many years and occurs in many stages. It is thought that breast cells destined to become cancer display changes that can be identified by laboratory tests before breast cancer occurs. Reversal of these changes by an agent such as selenium would suggest that we might be able to stop the cancer process. Due to selenium's antioxidant characteristics it may be possible to interrupt the chain of events that lead to breast cancer. The goal of this study is to determine whether taking selenium will decrease these cellular changes in the breast, blood, and urine, which may then help to decrease the risk of breast cancer.

##### Role of research subjects

- You will be asked to schedule three clinic visits; each visit is 6 months apart. At each visit you are asked to donate a sample of blood and to provide three first void urine specimens. At the first and last clinic visit, a sample of nipple aspirate fluid will also be obtained.
- You will be asked to take a selenium or placebo supplement along with a vitamin-mineral supplement on a daily basis for one year.
- You will be asked to update their BreastWatch questionnaire upon enrollment in the study, and again at the end of the study.

- You will be asked to discuss any questions or concerns with the Study Nurse Practitioner at any time. Also, you will be asked to update your health and pregnancy (if applicable) status at the monthly follow-up calls.

### **Costs of joining the study**

---

- There are no costs to participate in this study apart from the costs associated with your annual clinical visit, and your annual routine breast examination and mammography.

## **ENRICH** Selenium and Breast Cancer Chemoprevention

### **Participant Eligibility**

---

- Participant must be female
- Must be at least 21 years old
- Must regularly consume 2 or fewer alcoholic beverages per day
- Must be willing to limit alcohol consumption to 1 or less serving of alcohol per day (a serving is defined as: 12 oz. beer or 5 oz. wine or 1 oz of hard liquor)
- Must refrain from using tobacco products
- Must not take a specific selenium supplement, for example a supplement with more than 50 mcg/day selenium.
- Must be willing to discontinue taking other vitamin-mineral supplements and take the vitamin-mineral supplement prescribed for everyone in the study
- Must not be pregnant or lactating
- Must not intend to become pregnant during the study

### **Whom do I contact if I am interested in participating?**

---

Contact Becky Meinecke at (303) 242-3421 or (303) 336-5116 or email at [meinecke@amc.org](mailto:meinecke@amc.org)



## ELIGIBILITY FORM

---

### Inclusion Criteria:

- | <u>Yes</u>                       | <u>No</u>                        |   |
|----------------------------------|----------------------------------|---|
| <input type="radio"/>            | <input checked="" type="radio"/> | The subject must be female.   |
| <input type="radio"/>            | <input type="radio"/>            | The subject must be 21 or older. May I have your date of birth? <input type="text"/> / <input type="text"/> / <input type="text"/> (1981) |
| <input checked="" type="radio"/> | <input type="radio"/>            | Have you ever had a previous diagnosis of cancer (any type other than non-melanoma cancer)?   |

### Exclusion Criteria:

- | <u>Yes</u>                       | <u>No</u>                        |  |
|----------------------------------|----------------------------------|--|
| <input type="radio"/>            | <input checked="" type="radio"/> | Do you regularly consume 2 or fewer alcoholic beverages per day?   |
| <input type="radio"/>            | <input checked="" type="radio"/> | Are you willing to limit alcohol consumption to one drink or less per day?   |
| <input checked="" type="radio"/> | <input type="radio"/>            | Do you use tobacco products?   |
| <input checked="" type="radio"/> | <input type="radio"/>            | To your knowledge, are you currently pregnant?   |
| <input checked="" type="radio"/> | <input type="radio"/>            | Are you planning on becoming pregnant in the next 12 months?   |
| <input checked="" type="radio"/> | <input type="radio"/>            | Are you currently breastfeeding?   |
| <input type="radio"/>            | <input type="radio"/>            | Are you currently taking a multivitamin supplement   |
| <input type="radio"/>            | <input checked="" type="radio"/> | <b>If Yes:</b> Are you willing to stop taking your multivitamin supplement and take our standard daily multivitamin for the duration of the study?   |
|                                  |                                  | <b>If No:</b> Are you willing to take our standard daily multivitamin for the duration of the study?   |
| <input type="radio"/>            | <input type="radio"/>            | Are you currently taking a selenium supplement   |
| <input type="radio"/>            | <input checked="" type="radio"/> | <b>If Yes:</b> Are you willing to stop taking your selenium supplement during the study?   |
|                                  |                                  | <b>If No:</b> Will you agree not to start a selenium supplement during the study?  |
| <input type="radio"/>            | <input type="radio"/>            | Are you currently taking a vitamin E supplement?   |
| <input type="radio"/>            | <input checked="" type="radio"/> | <b>If Yes:</b> Are you willing to stop taking your vitamin E supplement during the study?  |
|                                  |                                  | <b>If No:</b> Will you agree not to start a vitamin E supplement during the study?   |
|                                  |                                  | <b>If Eligible:</b>  |
| <input type="radio"/>            | <input type="radio"/>            | Have you filled out a BreastWatch Questionnaire? (if No, fill out Enrich Patient History Questionnaire, if yes, fill out update Questionnaire)       |
| <input type="radio"/>            | <input type="radio"/>            | Subject is eligible for the study based in the inclusion and exclusion criteria. <i>A check in ANY shaded box means the subject is NOT eligible.</i> |
| <input type="radio"/>            | <input type="radio"/>            | Has informed consent been signed?  |









# Breast Watch

STUDY ID

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

22. Have you ever been told you had any of the following conditions?  Yes  No  
 If no, skip to question #23. If Yes, please complete the following table.

|   | Yes                     | Age Diagnosed        | No                    | Not Sure              |
|---|-------------------------|----------------------|-----------------------|-----------------------|
| Colon or rectal cancer                              | <input type="radio"/>   | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
| Endometrial cancer (cancer of the uterus)           | <input type="radio"/>   | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
| Ovarian cancer                                      | <input type="radio"/>   | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
| Fibrocystic breast condition                        | <input type="radio"/>   | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
| Breast cancer (If yes, please specify which breast) | R <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
|   | L <input type="radio"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
| Other breast problem                                | <input type="radio"/>   | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
| Other cancer <input type="text"/>                   | <input type="radio"/>   | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |

23. Have any of your relatives been diagnosed with cancer?  No  Yes

If YES, please complete the following charts for the relative affected.

Table key: B = Breast, O = Ovarian, P = Prostate, C = Colon Y = Yes, N = No, NS = Not Sure

| Relative                           | Type of Cancer          |                         |                         |                         | Was she still having periods |                       |                       | Age Diagnosed        | Did (S)he die of cancer? |                       |                       |
|------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|------------------------------|-----------------------|-----------------------|----------------------|--------------------------|-----------------------|-----------------------|
|                                    |                         |                         |                         |                         | Y                            | N                     | NS                    |                      | Yes                      | No                    | NS                    |
| <input type="radio"/> Mother       | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Father       | <input type="radio"/> B | <input type="radio"/>   | <input type="radio"/> P | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Sister #1    | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Sister # 2   | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Sister # 3   | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Brother # 1  | <input type="radio"/> B | <input type="radio"/>   | <input type="radio"/> P | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Brother # 2  | <input type="radio"/> B | <input type="radio"/>   | <input type="radio"/> P | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Brother # 3  | <input type="radio"/> B | <input type="radio"/>   | <input type="radio"/> P | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Daughter # 1 | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Daughter # 2 | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Daughter # 3 | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Son # 1      | <input type="radio"/> B | <input type="radio"/>   | <input type="radio"/> P | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Son # 2      | <input type="radio"/> B | <input type="radio"/>   | <input type="radio"/> P | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Son # 3      | <input type="radio"/> B | <input type="radio"/>   | <input type="radio"/> P | <input type="radio"/> C | <input type="radio"/>        | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |

# Breast Watch

STUDY ID

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

| Relative | Type of Cancer |  |  | Was she still having periods? |   |    | Age Diagnosed | Did (S)he die of cancer? |    |    |
|----------|----------------|--|--|-------------------------------|---|----|---------------|--------------------------|----|----|
|          |                |  |  | Y                             | N | NS |               | Yes                      | No | NS |

**Maternal Relatives (Mother's family)**

|                                     |                         |                         |                         |                         |                       |                       |                       |                      |                      |                       |                       |                       |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-----------------------|-----------------------|-----------------------|----------------------|----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> Grandmother   | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Grandfather   | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Aunt          | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Uncle         | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Female Cousin | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Male Cousin   | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Other         | <input type="text"/>    |                         |                         |                         |                       |                       |                       |                      |                      |                       |                       |                       |

**Paternal Relatives (Father's family)**

|                                     |                         |                         |                         |                         |                       |                       |                       |                      |                      |                       |                       |                       |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-----------------------|-----------------------|-----------------------|----------------------|----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> Grandmother   | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Grandfather   | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Aunt          | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Uncle         | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Female Cousin | <input type="radio"/> B | <input type="radio"/> O | <input type="radio"/> O | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Male Cousin   | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Other         | <input type="text"/>    |                         |                         |                         |                       |                       |                       |                      |                      |                       |                       |                       |

24 Have you ever had a breast cyst aspirated? (The insertion of a needle into your breast to remove some *fluid*)

No    Not sure    Yes

If yes, please specify

Left breast

How many times?

Right breast

How many times?

25 Have you ever had a breast biopsy? (A small incision or insertion of a needle into your breast to remove some *tissue*)

No    Not sure    Yes

If yes, please specify

Left breast

How many times?

Right breast

How many times?

# Breast Watch

STUDY ID

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

26 If possible, please list the date of each biopsy, the doctor who performed the procedure and his/her address, and the results.

1st biopsy

DATE  /  /

RESULTS  
 Benign (Non-cancerous)     Malignant (cancerous)

DOCTOR

ADDRESS

CITY  STATE  ZIP

2nd biopsy

DATE  /  /

RESULTS  
 Benign (Non-cancerous)     Malignant (cancerous)

DOCTOR

ADDRESS

CITY  STATE  ZIP

3rd biopsy

DATE  /  /

RESULTS  
 Benign (Non-cancerous)     Malignant (cancerous)

DOCTOR

ADDRESS

CITY  STATE  ZIP

4th biopsy

DATE  /  /

RESULTS  
 Benign (Non-cancerous)     Malignant (cancerous)

DOCTOR

ADDRESS

CITY  STATE  ZIP



# Breast Watch

STUDY ID

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

31. A serving of fruits or vegetables is defined as :

- a medium size apple
- cup of chopped vegetables or fruit
- 6 ounces of fruit juice

About how many servings of fruits and vegetables do you usually eat or drink in an average day? Please include both fruit, vegetables, and juice in your number.

# servings in an average day:

32. What concerns would you like to discuss with us regarding breast cancer?

---

---

---

---

---

33. What do you believe your personal risk for breast cancer is?

- Very high
- High
- Average
- Low
- Very low



# Breast Watch Update

STUDY ID

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

2. What is your marital status?

- Single (never married)
- Married
- Divorced
- Separated
- Widowed

4. What is the highest level of education you have completed?

- Elementary School (1 - 8 years)
- Some High School (9 - 11 years)
- High School Graduate (12 years)
- Some College, Associate Degree, Business or Technical (13-15 years)
- College Graduate (16 years)
- Post Graduate Training (17 + years)

8. Compared to other women your age, would you say your health is ...

- Excellent
- Good
- Fair
- Poor

9. Compared to a year ago, would you say your health is ...

- Better
- About the same
- Worse

13. How often do you perform breast self-examination to check for lumps or other changes?

- |  |   |
|--|---|
| <input type="radio"/> Never                                    | <input type="radio"/> 4-6 times a year                    |
| <input type="radio"/> Not in the past year                     | <input type="radio"/> 7-9 times a year                    |
| <input type="radio"/> Only when I suspect something unusual or | <input type="radio"/> 10-12 times a year                  |
| <input type="radio"/> 1-3 times a year                         | <input type="radio"/> More than 12 times in the past year |

20. Are you still having menstrual periods?

- |   |                                |
|---|--------------------------------|
| <input type="radio"/> Yes   | <input type="radio"/> Not sure |
| <input type="radio"/> Yes, but I am on estrogen replacement therapy | <input type="radio"/> No       |

If no, how old were you when you stopped having periods (either naturally or as a result of surgery)?

AGE

|  |  |
|--|--|
|  |  |
|--|--|

Not sure



# Breast Watch Update

STUDY ID

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

| Relative                           | Type of Cancer          |                         |                         |                         | Was she still having periods? |                       |                       | Age Diagnosed   | Did (S)he die of cancer? |                       |                       |
|------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------------|-----------------------|-----------------------|---|--------------------------|-----------------------|-----------------------|
|                                    |                         |                         |                         |                         | Y                             | N                     | NS                    |   | Yes                      | No                    | NS                    |
| <input type="radio"/> Brother # 2  | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                               |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Brother # 3  | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                               |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Daughter # 1 | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/>         | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Daughter # 2 | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/>         | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Daughter # 3 | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/>         | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Son # 1      | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                               |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Son # 2      | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                               |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Son # 3      | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                               |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/>    | <input type="radio"/> | <input type="radio"/> |

**Maternal Relatives (Mother's family)**

|                                     |                         |                         |                         |                         |                       |                       |                       |   |                       |                       |                       |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-----------------------|-----------------------|-----------------------|---|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> Grandmother   | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Grandfather   | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Aunt          | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Uncle         | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Female Cousin | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Male Cousin   | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

**Paternal Relatives (Father's family)**

|                                     |                         |                         |                         |                         |                       |                       |                       |   |                       |                       |                       |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-----------------------|-----------------------|-----------------------|---|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> Grandmother   | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Grandfather   | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Aunt          | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Uncle         | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Female Cousin | <input type="radio"/> B | <input type="radio"/> O |                         | <input type="radio"/> C | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| <input type="radio"/> Male Cousin   | <input type="radio"/> B |                         | <input type="radio"/> P | <input type="radio"/> C |                       |                       |                       | <input style="width: 20px; height: 20px;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

|                             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| <input type="radio"/> Other | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> | <input style="width: 20px; height: 20px;" type="text"/> |
|-----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|





# Breast Watch Update

STUDY ID

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

33. What do you believe your personal risk for breast cancer is?
- Very high
  - High
  - Average
  - Low
  - Very low



STUDY ID

Four empty boxes for study ID

MEDICATIONS AND SUPPLEMENTS QUESTIONNAIRE

PRESCRIPTION MEDICATIONS

Please record any prescription medication you take.

Name of prescription medicine #1: [grid], Dose [ ] mg, Number of pills [ ] [ ] each day, every other day, as needed

Length of time on medication [ ] [ ] days, months, years

Reason for taking medication: [grid]

Name of prescription medicine #2: [grid], Dose [ ] mg, Number of pills [ ] [ ] each day, every other day, as needed

Length of time on medication [ ] [ ] days, months, years

Reason for taking medication: [grid]

Name of prescription medicine #3: [grid], Dose [ ] mg, Number of pills [ ] [ ] each day, every other day, as needed

Length of time on medication [ ] [ ] days, months, years

Reason for taking medication: [grid]

Name of prescription medicine #4: [grid], Dose [ ] mg, Number of pills [ ] [ ] each day, every other day, as needed

Length of time on medication [ ] [ ] days, months, years

Reason for taking medication: [grid]

Name of prescription medicine #5: [grid], Dose [ ] mg, Number of pills [ ] [ ] each day, every other day, as needed

Length of time on medication [ ] [ ] days, months, years

Reason for taking medication: [grid]





**Use this letter for individuals who do not schedule their visit 1 appointment for the same day as their BreastWatch visit.**



1600 Pierce Street • Denver, Colorado 80214 • [www.amc.org](http://www.amc.org)

CENTER FOR NUTRITION IN THE PREVENTION OF DISEASE

**ENRICH**

Date

Name

Address

City State Zip

Dear Name:

I enjoyed talking with you recently about our ENRICH project. Our project team is delighted to know that you are interested in joining us in our research efforts to prevent and control the occurrence of breast cancer. We think that you will find our time together both challenging and rewarding. Through your efforts we hope to make progress toward important discoveries concerning nutrition and cancer prevention.

You are scheduled for your initial visit in Dr. Sedlacek's office on *date* at *time*. We expect this first visit to last between 90 minutes and 2 hours.

Enclosed with this letter is a brief description of ENRICH study and a copy of the Informed Consent document. We ask that you carefully read the Informed Consent documents. It contains critical information about your participation in our study. Please feel free to call me if you have any questions or concerns regarding this document. We will have time do discuss the Informed Consent on the day of your appointment.

We would also like to ask that you carefully fill out the medications and supplement forms we have included in your packet. It is very important for us to capture all medications and vitamin, mineral or herbal supplements that you are currently taking

If you have any questions, or should you need to re-schedule your appointment, please call me at (303) 336-5116. Once again, thank you for your interest. We look forward to seeing you.

Sincerely,

Becky Meinecke  
ENRICH Clinical Coordinator

Enclosures

**URINE COLLECTION INSTRUCTION SHEET**

Enclosed are four plastic containers (one large container and three small containers) for collecting and storing urine samples prior to your clinic visit scheduled on

□□ / □□ / □□ at □□ : □□  a.m.  p.m.

We ask you to collect your first urine void each morning on three consecutive days. Please carefully read the instructions for collection and storage of your urine samples. Please be sure to check your study calendar for the specific dates on which to collect your urine samples.

**INSTRUCTIONS FOR COLLECTING AND STORING THE URINE SAMPLES:**

• **Sample 1** Date to be collected: □□ / □□ / □□

1. After you wake up in the morning, collect your first morning void into the large plastic container.
2. Next, transfer 3 ounces or 90 ml of urine from the large container into the smaller container labeled **Sample 1**. To prevent overflow due to expansion upon freezing, do not fill the smaller container to above the 3 ounce mark. Be sure to screw the lid back on **tightly** to prevent leakage.
3. After the lid is on securely, write the date you collected the sample on the label on the Sample 1 container.
4. Next, place the labeled container in your **freezer**. The sample needs to be stored frozen until you bring it to Dr. Sedlacek's office on the day of your clinic visit.
5. The large container should be rinsed and reused to collect Samples 2 and 3.

**Sample 2** Date to be collected: □□ / □□ / □□

Follow the same instructions you followed for Sample 1 above. Except this time transfer 3 ounces or 90 ml of urine from the large container labeled Sample 2. Don't forget to write the date of the collection on the label on the Sample 2 container.

**Sample 3** Date to be collected: □□ / □□ / □□

Follow the same instructions you followed for Sample 1 above. Except this time transfer 3 ounces or 90 ml of urine from the large container labeled Sample 3. Don't forget to write the date of the collection on the label on the Sample 3 container.

**Date of clinic visit:** □□ / □□ / □□

Today is your clinic visit for the ENRICH Project. Please bring all three frozen urine samples to your clinic visit. Be sure to place them in the purple bag provided. It is very important that the samples are protected from excessive heat and direct sunlight during the transport.

If you have any questions, please contact Becky Meinecke, Clinical Coordinator, at 303-336-5116.

**YOUR PARTICIPATION IS GREATLY APPRECIATED.**





STUDY ID

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

**RANDOMIZATION FORM**

---

Date Randomization Completed

|  |  |   |  |  |   |  |  |
|--|--|---|--|--|---|--|--|
|  |  | / |  |  | / |  |  |
|--|--|---|--|--|---|--|--|

Date Density Analysis Completed

|  |  |   |  |  |   |  |  |
|--|--|---|--|--|---|--|--|
|  |  | / |  |  | / |  |  |
|--|--|---|--|--|---|--|--|

Breast Density

|  |  |      |  |  |       |
|--|--|------|--|--|-------|
|  |  | Left |  |  | Right |
|--|--|------|--|--|-------|

Gail Score

|  |  |
|--|--|
|  |  |
|--|--|

Color Code  
Assignment

- RED
- GREEN
- BLUE
- BLACK



STUDY ID  
[ ][ ][ ][ ]

Visit 1 Flowsheet

Date  
[ ][ ] / [ ][ ] / [ ][ ]

• Essential Forms:

Signed Consent form: [ ]  
Updated BreastWatch form: [ ]

Completed Eligibility form: [ ]  
Medication/Supplement form: [ ]

• Visit 1 Samples

Urine: [ ]

Menstrual History:

LMP: [ ][ ] / [ ][ ] / [ ][ ]

Pregnancy test [ ] Positive  
[ ] Negative

Cycle: [ ][ ] days [ ] Irregular

Blood:

Vital Signs:

1-EDTA tube: [ ]  
2-Paxgene tubes: [ ]  
4- CPT tubes: [ ]  
1-EDTA tube: [ ]  
Time drawn: [ ][ ] : [ ][ ]

Height: [ ] ft [ ][ ] in  
Weight: [ ][ ][ ] lbs  
Blood Pressure: [ ][ ][ ] / [ ][ ][ ]  
Pulse: [ ][ ][ ]

Nipple Aspirate Fluid: [ ] Yes [ ] No

Physical Exam: [ ][ ] / [ ][ ] / [ ][ ]

• Subject Handouts:

Pill Supply: [ ]

Sample Containers/

Study Calendar: [ ]

Instruction sheets: [ ]

Appointment card: [ ]

• Comments:

[ ]

Visit 2 Date: [ ][ ] / [ ][ ] / [ ][ ]

Appointment Time: [ ][ ] : [ ][ ] ○ a.m. ○ p.m.



STUDY ID

Visit 2 Flowsheet

Date

/   /

• Medical Screening:

Medication and Supplement Questionnaire:

Physical Exam:

Last month study tablets

Last month multivitamins

*When do you usually take your study tablets?*

- breakfast
- lunch
- dinner
- bedtime

• Visit 2 Samples

Urine:    Visit one urine:

Date urine received:

/   /

Blood:

Vital Signs:

1-EDTA tube:

Height:   .  in

2-Paxgene tubes:

Weight:    lbs

4- CPT tubes:

Blood Pressure:    /

1-EDTA tube:   
Time drawn:   :

Pulse:

• Subject Handouts:

Pill Supply:

Sample Containers/  
Instruction sheets:

Study Calendar:

• Comments:

Visit 3 Date:   /   /

Appointment Time:   :    a.m.  p.m.

Mammogram Ordered:   /   /



|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

## STUDY TABLET DISTRIBUTION & RECONCILIATION

Study Tablet Color Code:  Red  Green  Blue  Black

| Study Tablet Bottle | Study Tablet ID Number | Date Issued | Date Returned | Quantity Dispensed | # of tablets prescribed | # of tablets left in bottle | # of tablets taken | % compliance |
|---------------------|------------------------|-------------|---------------|--------------------|-------------------------|-----------------------------|--------------------|--------------|
| 1                   |                        |             |               | 40                 |                         |                             |                    |              |
| 2                   |                        |             |               | 40                 |                         |                             |                    |              |
| 3                   |                        |             |               | 40                 |                         |                             |                    |              |
| 4                   |                        |             |               | 40                 |                         |                             |                    |              |
| 5                   |                        |             |               | 40                 |                         |                             |                    |              |
| 6                   |                        |             |               | 40                 |                         |                             |                    |              |
| 7                   |                        |             |               | 40                 |                         |                             |                    |              |
| 8                   |                        |             |               | 40                 |                         |                             |                    |              |
| 9                   |                        |             |               | 40                 |                         |                             |                    |              |
| 10                  |                        |             |               | 40                 |                         |                             |                    |              |
| 11                  |                        |             |               | 40                 |                         |                             |                    |              |
| 12                  |                        |             |               | 40                 |                         |                             |                    |              |
| 13                  |                        |             |               | 40                 |                         |                             |                    |              |

## MULTIVITAMIN DISTRIBUTION & RECONCILIATION

| Multi-vitamin Tablet Bottle | Date Issued | Date Returned | Quantity Dispensed | # of tablets prescribed | # of tablets left in bottle | # of tablets taken | % compliance |
|-----------------------------|-------------|---------------|--------------------|-------------------------|-----------------------------|--------------------|--------------|
| 1                           |             |               |                    |                         |                             |                    |              |
| 2                           |             |               |                    |                         |                             |                    |              |



STUDY ID  
[ ][ ][ ][ ]

Date  
[ ][ ] / [ ][ ] / [ ][ ]

**Monthly Telephone Contact Form**

---

• Health status:

Compared to a month ago, would you say your health is ...

- Better     About the same     Worse

Comments

---

• Reproductive Status (Only ask this question of women that reported that they are still menstruating naturally)

Do you have any reason to believe that you may be pregnant?

- Yes     No

• Compliance Status:

Are you taking your study tablet and multivitamin-mineral supplement daily?

- Yes     No

Are you experiencing any difficulty in taking your study tablet or multivitamin supplement?

- Yes     No

Have you returned your unused bottles of tablets for this month using the self-addressed mailer?

- Yes     No

Do you know the physical location (in your home) of the bottles of study tablets and multivitamin-mineral supplements that you will be using next month?

- Yes     No

• Comments:

|  |  |  |  |
|--|--|--|--|
|  |  |  |  |
|--|--|--|--|

---

**Adverse Events**

---

Date Reported

|  |  |   |  |  |   |  |  |
|--|--|---|--|--|---|--|--|
|  |  | / |  |  | / |  |  |
|--|--|---|--|--|---|--|--|

**Nipple Aspirate Fluid:**

- Bruising  
 Tenderness  
 Other (please Specify):

|  |
|--|
|  |
|--|

**Blood Samples:**

- Hematoma large  
 Infection  
 Other (please specify):

|  |
|--|
|  |
|--|

**Selenium:**

- |                                |                                    |   |
|--------------------------------|------------------------------------|---|
| <input type="radio"/> Nausea   | <input type="radio"/> Skin Rash    | <input type="radio"/> Muscle weakness     |
| <input type="radio"/> Anxiety  | <input type="radio"/> Depression   | <input type="radio"/> Liver abnormalities |
| <input type="radio"/> Sweating | <input type="radio"/> Brittle hair | <input type="radio"/> Garlic breath       |
| <input type="radio"/> Vomiting | <input type="radio"/> Nail Changes | <input type="radio"/> Other:              |

|  |
|--|
|  |
|--|

**Other unanticipated reactions:**

|  |
|--|
|  |
|--|



Irregular Sample Loglog



1600 Pierce Street • Denver, Colorado 80214 • www.amc.org

CENTER FOR NUTRITION IN THE PREVENTION OF DISEASE



**To:**

**To:**

**From:**

**From:**

**Subject ID:**

**Subject ID:**

**Date:**

**Date:**

**Clinical Comments:**

**Laboratory Comments:**

ENRICH DATA DICTIONARIES

ELIGIBILITY

| Variable name | Type and size | Required | format             | Comments/label  |
|---------------|---------------|----------|--------------------|---|
| ENRICHID      | I 4           |          | F4.0               | autofill<br><b>Enrich ID</b>  |
| ENRDATE       | Mmddyy10.     |          | Mmddyy10           | Auto fill<br><b>Date Enrolled</b>   |
| SEX           |               | R        | 1=Female<br>0=Male | Default=1   |
| OVER21        | I4            | R        | 1=Yes<br>0=No      | Over 21   |
| DOB           |               | R        | Mmddyy10.          |   |
| AGE           |               |          |                    | floor<br>((intck('month',DOB,TODAY())<br>- (day(TODAY()) < day(DOB))) /<br>12)  |
| HxCA          |               | R        | 1=Yes<br>0=No      | <b>History of Cancer</b>  |
| ALCOHOL       |               | R        | 1=Yes<br>0=No      | <b>Alcohol GT 2/day</b>   |
| LMTALC        |               | R        | 1=Yes<br>0=No      | <b>Will Limit Alcohol</b>   |
| TOBACCO       |               | R        | 1=Yes<br>0=No      | <b>Uses Tobacco</b>   |
| PREGNANT      |               | R        | 1=Yes<br>0=No      | <b>Pregnant</b>   |
| PLANPREG      |               | R        | 1=Yes<br>0=No      | <b>Plan Preg in 12 mon</b>  |
| BRFEED        |               | R        | 1=Yes<br>0=No      | <b>Breast Feeding</b>   |
| MULTI         |               | R        | 1=Yes<br>0=No      | <b>MultiVitamins</b>  |
| STUDYSUPP     |               | R        | 1=Yes<br>0=No      | <b>Will Take Study MV</b>   |
| SESUPP        |               | R        | 1=Yes<br>0=No      | <b>Se Supplement</b>  |
| QTSESUPP      |               | R        | 1=Yes<br>0=No      | <b>Will Stop Se</b>   |
| ESUPP         |               | R        | 1=Yes<br>0=No      | <b>Vit E Supplement</b>   |
| QTESUPP       |               | R        | 1=Yes<br>0=No      | <b>Will Stop Vit E</b>  |
| ELIGIBLE      |               |          | 1=Yes<br>0=No      | Autofill: 1<br>If SEX=1 and age>=21 and<br>HxCA=0 and ALCOHOL=0 and<br>TOBACCO=0<br>and LMTALC=1 and<br>PREGNANT=0<br>and BRFEED=0 and<br>PLANPREG=0<br>and STUDYSUPP=1 and<br>QTSESUPP=1 and QTESUPP=1<br><br>else 0 |
| BWQ           |               |          | 1=Yes<br>0=No      | If 1, go to KEYSN and read<br>LNAME   |

|           |          |  |               |   |
|-----------|----------|--|---------------|---|
|           |          |  |               | <p>lookup in KEYSBW and print selection of LNAMEs for choice; if no matching LNAME, assign next ID in sequence; update or add contact info. COPY TO KEYSSEN.</p> <p>If 0, go to <i>add record</i> in KEYSSEN and assign next ID in sequence (3001, ...); do not allow exit without LNAME, FNAME, and at least one of HPHONE, WPHONE</p> <p><b>BreastWatch</b></p> |
| CONSENT   |          |  | 1=Yes<br>0=No | <b>Consent Signed</b>   |
| VISIT1APP | Mmddy10. |  | Mmddy10.      | <b>Appt Date V1</b>   |
| V1APPTM   | HH:MM    |  | HH:MM         | Integer fmt OK – will not be used in computations<br><b>Appt Time V1</b>  |
| V1APPAMPM | \$2      |  | AM<br>PM      | <b>AMPM V1</b>  |

CONTACT ( KEYSBW)

| Variable name | Type and size | format                 | Comments/label   |
|---------------|---------------|------------------------|--|
| ROSEID        | I 4           | F4.0                   | Autofill (key field)<br><b>BreastWatch ID</b>              |
| LNAME         | \$20          |                        | <b>Last Name</b>   |
| FNAME         | \$20          |                        | <b>First Name</b>  |
| MI            | \$1           |                        | <b>MI</b>  |
| DOB           | Num 8         | DATETIME20             | <i>Between 1917 and 1981</i><br><b>Date of Birth</b>       |
| ADDRESS       | \$40          |                        | <b>Address</b>   |
| CITY          | \$20          |                        | <b>City</b>  |
| STATE         | \$2           |                        | <b>State</b>   |
| ZIP           | ZIP           | \$5                    | <b>Exactly 5 digits</b><br><b>Zip Code</b>                 |
| HOMEPHONE     | PHONE#        | \$15                   | <i>Exactly 10 digits</i><br><b>Home Phone</b>              |
| WORKPHONE     | PHONE #       | \$15                   | <i>Exactly 10 digits</i><br><b>Work Phone</b>              |
| SSN           | SSN           | \$11                   | <b>Exactly 9 digits</b><br><b>SSN</b>                      |
| CELL          | PHONE#        | \$15                   | <i>Exactly 10 digits</i><br><b>Cell Phone</b>              |
| EMAIL         | \$20          | \$20                   | <b>Email Address</b>                                       |
| DATE          | Num 8         | DATETIME20             | <i>Earlier than TODAY()</i><br><b>DATE</b>                 |
| UPDATE        | Num 8         | DATETIME20             | <i>Earlier than TODAY()</i><br><b>Last Update</b>          |
| STATUS        | I1            | 1=Active<br>0=inactive | <i>Default=1 (no missing)</i><br><b>BreastWatch Status</b> |

CONTACT ( KEYSSEN)

| Variable name | Type and size | format | Comments/label |
|---------------|---------------|--------|----------------|
|---------------|---------------|--------|----------------|

|           |         |                         |   |
|-----------|---------|-------------------------|---|
| ENRICHID  | I 4     | F4.0                    | Autofill (key field)<br><b>Enrich ID</b>  |
| LNAME     | \$20    |                         | <b>Last Name</b>  |
| FNAME     | \$20    |                         | <b>First Name</b>   |
| MI        | \$1     |                         | <b>MI</b>   |
| DOB       | Num 8   | DATETIME20              | <i>Between 1917 and 1981</i><br><b>Date of Birth</b>                              |
| ADDRESS   | \$40    |                         | <b>Address</b>  |
| CITY      | \$20    |                         | <b>City</b>   |
| STATE     | \$2     |                         | <b>State</b>  |
| ZIP       | ZIP     | \$5                     | <b>Exactly 5 digits</b><br><b>Zip Code</b>  |
| HOMEPHONE | PHONE#  | \$15                    | <i>Exactly 10 digits</i><br><b>Home Phone</b>                                     |
| WORKPHONE | PHONE # | \$15                    | <i>Exactly 10 digits</i><br><b>Work Phone</b>                                     |
| SSN       | SSN     | \$11                    | <b>Exactly 9 digits</b><br><b>SSN</b>   |
| CELL      | PHONE#  | \$15                    | <i>Exactly 10 digits</i><br><b>Cell Phone</b>                                     |
| EMAIL     | \$20    | \$20                    | <b>Email address</b>  |
| DATE      | Num 8   | DATETIME20              | <i>Earlier than TODAY()</i><br><b>DATE</b>  |
| UPDATE    | Num 8   | DATETIME20              | <i>Earlier than TODAY()</i><br><b>Last Update</b>                                 |
| ENSTATUS  | I1      | 1=Active<br>0=Withdrawn | Default=1. Change to 0 triggered by study withdrawal form<br><b>Enrich Status</b> |

#### RANDOMIZATTION

| Variable name | Type and size | format                                  | Comments/label  |
|---------------|---------------|---|---|
| ENRICHID      | I 4           | F4.0                                    | Keyboard entry, lookup LNAME and print to screen for verification.<br>Check ELIGIBILITY table: ELIGIBLE=1 and CONSENT=1 else error message to screen.<br><b>Enrich ID</b>   |
| LDENSITY      | I 2           | F2.0                                    | <b>Density Left</b>   |
| RDENSITY      | I 2           | F2.0                                    | <b>Density Right</b>  |
| GAIL          | R 4           | F4.2                                    | <b>Gail Score</b>   |
| COLOR         | I 1           | 1=RED<br>2=BLUE<br>3=YELLOW<br>4=ORANGE | Autofill based on stratification: Blocks of 10<br>Assign 2 colors to TX and 2 to PBO<br><b>CLASSIFIED INFORMATION REQUIRES PASSWORD</b><br><br>DENSITY=MAX(LDENSITY,RDENSITY)<br><br>4 Strata:<br>DENSITY<br><b>[0-5] (5-10)]</b><br>GAIL<br><b>(0- 3.2](3.2- 20)</b><br><b>Randomization Group</b> |
| DENSITY       | R 2           | F3.1                                    | Computed and stored, appears on screen but no access from keyboard<br><b>MAX Density</b>  |
| RANDDATE      | Mmddy10.      | mmdyy10                                 | Auto fill<br><b>Date Randomized</b>   |
| EXAMDATE      | Mmddy10.      | MMDDYY10.                               | Date density was measured<br><b>Date of Last Physical Exam</b>  |

VISIT 1 FLOW SHEET

| Variable name | Type and size | format                     | Comments/label  |
|---------------|---------------|----------------------------|---|
| ENRICHID      | I 4           | F4.0                       | Keyboard entry, lookup LNAME and print to screen for verification<br><b>Enrich ID</b> |
| VISITDATE     | Mmddy10.      | Mmddy10.                   | <i>Earlier than TODAY()</i><br><b>Visit Date</b>                                      |
| URINE         | I1            | 1=Yes<br>0=No              | <b>Urine Sample</b>   |
| PREGTEST      | I1            | 1=Positive<br>0=Negative   | <b>PregTest Results</b>   |
| LMP           | Mmddy10.      | MMDDYY10.                  | <i>Earlier than TODAY()</i><br><b>Last Menstrual Period</b>                           |
| CYCLE         | I2            | F2.0                       | <b>Menstrual Cycle</b> valid: x - xx ?  |
| IRREGULAR     | I1            | 1=Checked<br>0=Not Checked | <b>Irregular Cycle</b>  |
| EDTA1         | I1            | F1.0                       | <b>EDTA Tube 1</b> valid: 0, 1  |
| PAXGENE       | I1            | F1.0                       | <b>Paxgene Tubes</b> valid: 0, 1, 2   |
| CPT           | I1            | F1.0                       | <b>CPT Tubes</b> valid 0, 1, 2, 3, 4  |
| EDTA2         | I1            | F1.0                       | <b>EDTA Tube 2</b> valid: 0, 1  |
| HEIGHTFT      | R4            | F1.0                       | <b>Height (Feet part)</b> valid:4 - 7?  |
| HEIGHTIN      | R4            | F3.1                       | <b>Height (Inches part)</b> valid 0.0-11.9  |
| WEIGHT        | R4            | F4.1                       | <b>Weight in Pounds</b> valid 90-400 ?  |
| SYSTBP        | I3            | F3.0                       | <b>Systolic BP</b> valid xx-xxx ?   |
| DIASBP        | I3            | F3.0                       | <b>Diastolic BP</b> valid xx- xxx ?   |
| PULSE         | I3            | F3.0                       | <b>Pulse Rate</b> valid 50-100 ?  |
| NIPPASP       | I1            | 1=Yes<br>0=No              | <b>Nipple Aspiration</b>  |
| EXAMDATE      | Mmddy10.      | Mmddy10.                   | <i>Earlier than TODAY()</i><br><b>Date of CBE</b>                                     |
| VISIT2APP     | Mmddy10.      | Mmddy10.                   | <b>Appt Date V2</b>   |
| V2APPTM       | HH:MM         | HH:MM                      | Integer fmt OK – will not be used in computations<br><b>Appt Time V2</b>              |
| V2APPAMPM     | \$2           | AM<br>PM                   | <b>AMPM V2</b>  |
| VISIT         |               |                            | Auto fill value= 1  |

| Variable name | Type and size | format  | Comments/label   |
|---------------|---------------|---|--|
| ENRICHID      | I 4           | F4.0  | <i>Enrich ID</i>   |
| DATE          | Mmddy10.      | Mmddy10.  | <i>Earlier than TODAY()</i><br><b>Date of exam</b>   |
| HEIGHTFT      | R4            | F1.0  | <b>Height (Feet)</b> valid:4 - 7?  |
| HEIGHTIN      | R4            | F3.1  | <b>Height (Inches)</b> valid 0.0-11.9  |
| WEIGHT        | R4            | F4.1  | <b>Weight in Pounds</b> valid 90-400 ?   |
| VISIT         | I2            | F2.0  | <i>Visit number</i>  |
| CBER          | I 1           | 1=Normal<br>2=Abnormal, no change<br>3=Abnormal, new change<br>4=Abnormal, suspicious   | <b>Clinical breast exam right</b>  |
| CBEL          | I 1           | 1=Normal<br>2=Abnormal, no change<br>3=Abnormal, new change<br>4=Abnormal, suspicious   | <i>Clinical breast exam left</i>   |
| RMAMMDATE     | Mmddy10.      | Mmddy10.  | <b>Earlier than TODAY()</b><br><i>Right mamm date</i>  |
| RDENSITY      | I 2           | F2.0  | <b>Density Right</b>   |
| RRESULTS      |               | 1=Normal<br>2=Abnormal, no change<br>3=Abnormal, new change<br>4=Abnormal, suspicious   | <i>Right mammogram results</i>   |
| LMAMMDATE     | Mmddy10.      | Mmddy10.  | <i>Earlier than TODAY()</i><br><b>Left mamm date</b>   |
| LDENSITY      | I 2           | F2.0  | <b>Density Left</b>  |
| LRESULTS      | I 1           | 1=Normal<br>2=Abnormal, no change<br>3=Abnormal, new change<br>4=Abnormal, suspicious   | <b>Left mammogram results</b>  |
| RPATHDATE     | Mmddy10.      | Mmddy10.  | <i>Earlier than TODAY()</i><br><b>Right pathology date</b>   |
| RPATHRES      | I 2           | 1=No Diag Features<br>2=Fibroadenoma<br>3=Fibrocystic Change<br>4=Hyperplasia<br>5=Atypical Hyperplasia<br>6=LCIS<br>7=DCIS<br>8=Cancer<br>10=Other | <i>If other, the written response is not entered . We can generate a list of IDs, or names, where other was checked.</i><br><br><b>Right pathology results</b> |
| LPATHDATE     | Mmddy10.      | Mmddy10.  | <i>Earlier than TODAY()</i><br><b>Left pathology date</b>  |
| LPATHRES      | I 1           |   | <b>Left pathology results</b>  |
| FOLLDATE      | Mmddy10.      | Mmddy10.  | <i>Later than TODAY()</i><br><b>Follow up appointment date</b>   |
| FU1           | I 1           | 1=Yes   | <b>Needs follow up visit</b>   |
| FU2           | I 1           | 1=Yes   | <b>Follow up with PCP</b>  |
| FU3           | I 1           | 1=Yes   | <b>Send letter in 6 mo. (have no idea what this is for)</b>  |
| FU4           | I 1           | 1=Yes   | <b>Patient needs mammogram</b>   |
| FU5           | I 1           | 1=Yes   | <b>Patient does not need mammogram</b>   |

ENRICH DATA SOURCES  
BREASTWATCH.MDB (lap top)

| TABLE NAME   | Set up and programming | LINKING ELEMENTS  |
|--|------------------------|---|
| KEYSBW   | Brett                  | ROSEID unique subject id (key field)<br>SSN<br>DOB              |
| BWQUEST  | Brett                  | ROSEID unique subject id (key field)<br>SSN<br>DOB              |
| BWQUESTUPD<br>(we will just edit BWQUEST – question numbers correspond)    | NA                     | ROSEID unique subject id<br>SSN<br>DOB                          |
| PHYSICAL EXAM<br>(form and screen in place – may need a few modifications) | JOHN                   | ROSEID unique subject id<br>DATE date of exam<br>A compound key |
| INACTIVE   | NA                     | ROSEID unique subject id<br>SSN<br>DOB                          |

ENRICH.MDB (lap top)

| TABLE NAME                         | Set up and programming             | LINKING ELEMENTS  |
|------------------------------------|------------------------------------|---|
| KEYSEN                             | LORI (copy in from Brett's KEYSBW) | ENRICHID unique subject ID<br>SSN<br>DOB  |
| ELIGIBILITY                        | LORI                               | ENRICHID unique subject id<br>DOB   |
| RANDOMIZATION                      | LORI                               | ENRICHID unique subject ID  |
| PHYSICAL EXAM                      | JOHN                               | ENRICHID unique subject ID<br>DATE<br><b>A compound key</b>                               |
| VISIT1FLOW                         | JOHN                               | ENRICHID unique subject ID  |
| VISIT2FLOW                         | JOHN                               | ENRICHID unique subject ID  |
| VISIT3FLOW                         | JOHN                               | ENRICHID unique subject ID  |
| ENRICHQUEST<br>(duplicate BWQUEST) | JOHN                               | ENRICHID unique subject ID  |
| ADVERSE EVENTS                     | JOHN                               | ENRICHID unique subject ID  |
| MEDSUPP                            | JOHN                               | ENRICHID unique subject ID  |
| WITHDRAWAL                         | JOHN                               | ENRICHID unique subject ID  |
| STUDYTABLETS                       | JOHN                               | ENRICHID unique subject ID<br>RAND random number on tablet label<br><b>A compound key</b> |
|                                    |                                    | ENRICHID unique subject ID  |

ENRICH LAB DATA (novell server)

| FILE NAME     |      | LINKING ELEMENTS                        |
|---------------|------|---|
| RANDOMIZATION | JOHN | RAND random number on tablet label      |
| SELENIUM.XLS  | ZHU  | ENRICHID unique subject ID<br>ACCESSION |
| CYTOLOGY      | JOHN | ENRICHID unique subject ID<br>ACCESSION |
| OHdG          | AL   | ENRICHID unique subject ID<br>ACCESSION |
| EPG           | AL   | ENRICHID unique subject ID<br>ACCESSION |