BRCA1/2 Mutation Carrier Studies
REVISED DATA DICTIONARY
(May 2007- version 1.0)

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Notes
We will now be collecting all variables on all women eligible for PROSE and Modifiers/MAGIC.

****PLEASE NOTE: The following pertains to all DATES – if only the year is given, 1997, input the midpoint of the year – 7/1/1997. If the month and year are available, input the midpoint of the month. So if I have March 1950, I input 3/15/1950.**

i=1,2,3 (start of …1st incidence)

Please note: throughout the codebook there are certain categories that it is possible to have more than one occurrence. If the code has a i on the end of it, as many occurrences as possible can be recorded. The variables are listed once in the codebook for simplicity, but the database can capture multiple uses if the variable code is followed by a i. Ex: PMPATHi, BCDATEi, BCPBEGi etc…)

Please see changes for data collection in red

For Penn use only:
UT updated: Open text

Requests: Open text

Use: Open text

Status: Open text

PART 1: IDENTIFIER INFORMATION

VARIABLE	DESCRIPTION (CODING SCHEME)
UID	Unique identifier (formed by some combination of a center+family+individual code) Format: Two letter center code, 5 digits for fam & 5 digits for ego – fill in gaps with zeros. **Ex:** CID: UP, FAM: 22; EGO: 451; **UID= UP0002200451**
Study	**1=PROSE** **2=Modifiers** **3=Both** **4=None- not eligible for either study**
CID	Center Identification: Required AU= Austria BA= Baylor College of Medicine-Houston (Plon) BI = Beth Israel Medical Center BU= Baylor University Medical Center-Dallas (Blum) CH= City of Hope CR= Creighton DF= Dana Farber DU= Duke EH= Evanston Northwestern Healthcare EF= Israel, Chaim Sheba Medical Center (Eitan Friedman) FC= Fox Chase Cancer Center GU= Georgetown University KF=Australia, kConFab LA= University if California, Los Angeles MC= Mayo Clinic NK= Netherlands Cancer Institute RM= Royal Marsden SM= St. Mary's SW= UTSouthwest UC= University of Chicago UP= University of Pennsylvania UT= University of Utah/now at Univ. of California, Irvine WC=Women's College Hospital, Toronto YA= Yale University
FAM	Original number assigned to each family, Required except NK & BI, which do not have FAM
EGO	Original number assigned to each individual in the pedigree, Required
MainID	local ID number from Center
LABNUM	Center lab number **(could be UID)**
RACE	Race/Ethnicity of the subject: 1=Caucasian, non-Jewish and non-Hispanic

2=African American/Black
3=Native American
4=Asian/Pacific Islander
5=Jewish
6=Black Hispanic
7=Caucasian Hispanic
8=Indian/Pakistani/South Asian
9=Other
99=Missing

Ethnic$_i$ Ethnic background, i=1-4 to include reports of up to 4 ethnicities

01 African American
02 American Indian
03 Armenian
04 Jewish - Ashkenazi
05 Austrian
06 Belge
07 Bulgarian
08 Caucasian/Unknown
09 Croatia
10 Czech Republic
11 Denmark
12 Egyptian
13 English
14 Estonia
15 European Block Countries
16 French
17 German
18 Greek
19 Hispanic
20 Hungary
21 India
22 Iranian
23 Iraqi
24 Irish
25 Italian
26 Japanese
27 Jewish - unspecified
28 Lebanese
29 Lybian
30 Malta
31 Mexican
32 Dutch
32 Netherlands (Dutch)
33 Norway
34 Polish
35 French Canadian
35 Québécois
36 Russian
37 Scandinavian
38 Scottish
39 Jewish - Sephardic
40 South American
41 Spanish
42 Swedish
43 Swiss
44 Trinidad
45 Turkish
46 Ukrainian
47 Welsh
48 Danish
49 Romanian
50 New Zeland
51 Yugoslavia
52 Australia
54 Asian

(The following pertains to all DATES – if only the year is given, like 1997, I input the midpoint of the year – 7/1/1997. If the month and year are available, I input the midpoint of the month. So if I have March 1950, I input 3/15/1950.)

DOB Date of birth: MM/DD/YYYY (You may enter partial information for this and all subsequent requested dates. For example, if you only had the year of birth, enter 7/1/YYYY, or if you only had the month and year, enter MM/15/YYYY.) Required.

ADATE Date of ascertainment of the family (i.e. date at which the proband in the family was ascertained): MM/DD/YYYY

MFDATE Date in which family's mutation testing result was first disclosed: MM/DD/YYYY

ITDATE Date in which individual's mutation testing was first disclosed: MM/DD/YYYY; if subject deceased or does not want to be informed please enter 99/99/9999 and record the actual test date below. (reworded)

TestDate Date of the actual test MM/DD/YYYY that discovered the positive mutation (if more than one testing date, use the earliest POSITIVE test date, we will not record negative tests) (new variable)

EnrollmentDate(Utah) Date of the enrollment for research at Utah MM/DD/YYYY (new variable)

Edu Highest level of education
1 grade school/junior high
2 some high school
3 high school graduate
4 technical/vocational beyond high school
5 some college
6 college graduate
7 some post graduate
8 post graduate degree
9 missing/ unknown

PART 2: PROPHYLACTIC SURGERY HISTORY

VARIABLE DESCRIPTION (CODING SCHEME)

ProphBreast Ever have any prophylactic surgery of the breast?
1= Yes, 2= No, 9= missing

BSDATE1 Date of first prophylactic surgery of the breast: MM/DD/YYYY, 99/99/9999=unknown 00/00/0000=no prophylactic surgery

BSITE1 Site of First Prophylactic Surgery - Breast, coded as follows:
BB = Bilateral Breast
UL = Unilateral Prophylactic Mastectomy in the Left Breast
UR = Unilateral Prophylactic Mastectomy in the Right Breast
UM = Unilateral Prophylactic Mastectomy, Laterality Unknown
XX = Missing
NO =None

BSTYPE1 Type of First Breast Surgery, coded as follows:
MR=Modified Radical Mastectomy (removal of breast, overlying skin and axillary lymph nodes)
QM=Subcutaneous Mastectomy (removal of breast with preservation of overlying skin)
RM=Radical Mastectomy (removal of breast, overlying skin, pectoralis muscles and axillary contents)
SM=Simple Mastectomy (removal of breast and overlying skin)
OM=Other Mastectomy
UM=Unspecified Mastectomy
NO=None

XX=missing

BSURG1 Indications for first prophylactic breast surgery:
1= preventive, mutation carrier, with positive family history
2= preventive, mutation carrier, without positive family history
3=preventive, positive family history, unknown mutation status
5=diagnosis of breast cancer leading to the removal of the contralateral breast
6=other (specify)
8=no prophylactic breast surgery, NA, Not Applicable
9=missing

BScomment: open text (new variable)

BSDATE2 Date of second prophylactic surgery (same coding as 'BSDATE1')

BSITE2 Site of Second Prophylactic Surgery (same coding as 'SITE1')

BSTYPE2 Type of Second Breast Surgery (same coding as "BSTYPE1")

BSURG2 Indicators for second prophylactic breast surgery (same coding as 'BSURG1')

ProphOvary Ever have any prophylactic surgery of the ovaries?
1= Yes, 2= No, 9= missing

OSDATE1 Date of first (prophylactic) surgery of the ovaries: MM/DD/YYYY, 99/99/9999=unknown 00/00/0000=no prophylactic surgery.

OSTYPE1 Type of first ovarian surgery
BO=Bilateral Oophorectomy – method unknown
BOL=Bilateral Oophorectomy – laproscopy
BOI = Bilateral Oophorectomy – abdominal incision
UO=Unilateral Oophorectomy
~~UU=Oophorectomy Status Unknown (delete)~~
UOHY=Unilateral Oophorectomy with hysterectomy
HY=Bilateral Oophorectomy with Hysterectomy
NO=None
XX=missing

TUBE1 Status of Fallopian Tubes in the ovarian surgery
Y = Both fallopian Tubes removed
N = Fallopian Tubes not removed
U = From medical records, unknown whether fallopian tubes were removed or not
L = only left fallopian tube removed

R = only right fallopian tube removed

XX = Missing

OSURG1 Indicators for (prophylactic) ovarian surgery:
1=preventive, mutation carrier, with positive family history
2=preventive, mutation carrier, without positive family history
3=preventive, Positive family history, unknown mutation status
5=as part of a hysterectomy or not specifically prophylactic for cancer
6=other (specify):
601 cancer
602 fibroma
603 cyst
604 bleeding prevention
605 prolapse uterus/bladder
606 abnormal pap/CA 125
607 tumor & hemorrhage
608 tumor
609 scar tissue
610 ectopic pregnancy
611 menstrual difficulties
612 Infection
613 endometriosis
614 dylspalsia
615 headaches
616 bladder problems
617 Pain
618 Treatment for cancer other than breast or ovarian
619 Breast Cancer Treatment
620 Ovarian Cyst of condition unrelated to cancer
621 Multiple reasons
699 Missing
8=no prophylactic ovarian surgery, NA, not applicable
9=missing

OScomment open text (new variable)

OSDATE2 Date of second ovarian prophylactic surgery (same coding as “OSDATE1”)

OSTYPE2 Type of Second Ovarian Surgery (same coding as ‘TYPE1’)

TUBE2 Status of Fallopian Tubes in Ovarian Surgery

OSURG2 Indicators for second prophylactic ovarian surgery (same coding as ‘OSURG1’)

Tubal Did the subject ever have a tubal ligation?
1= Yes, 2= No, 3=Unilateral tube only, 9= missing

TubalYr In what year did the subject have a tubal ligation? YYYY, 0=no tubal ligation; 9999=missing

TUBALcomment open text (new variable)

SurgRep1 Did the subject ever have any surgery on her reproductive organs (please include prophylactic surgery if uterus was removed)?
1= Yes, 2= No, 9= missing

SurgTyp1 Type of operation performed

00 none	08 hyst + bil ooph.	16 Fallop. Tube removed
01 cryosurgery	09 laser	17 biopsy
02 hysterectomy	10 bil. ooph & appendix	18 conization
03 c-section(s)	11 laparoscopy	19 chloecystectomy
04 ovarian cysts	12 oophorectomy	20 rem of ectopic preg
05 rem. of Barthalon gland	13 cervix removed	21 Hystero salpinogram
06 d+c	14 laparotomy	22 salpinogram
07 rem. of scar tissue	15 mymectomy	23 rem. of uterine polyps
97 other	99 Missing	

SurgYr1 Year of first reproductive organ surgery: YYYY, 9999=unknown, 0=no surgery

SurgRea1 Reason for surgery

00 none	11 tumor	22 exploratory
01 pre-cancer cells	12 cyst	23 polyps
02 endometriosis	13 cancer	24 blocked tubes
03 prevention	14 bleeding	25 dysplasia
04 fibroma/fibroids	15 abnormal PAP/Ca125	26 pelvic inflam dis (PIV)
05 no more kids	16 cervical in-situ	27 Heavy menstrual flow
06 baby in distress/problems	17 exploratory	28 Tubal pregnancy
07 miscarriage	18 prolapsed bladder	29 Myomas
08 painful scar tissue	19 papilloma virus	30 Painful periods
09 prolapse of uterus	20 vaginal cysts	31 Menstrual cycle prob.
10 enlarged uterus	21 adhesions	32 Pain
97 other	99 missing	

SURGcomment open text (new variable)

SurgRep2 (same coding as SurgRea1) (new variable)

SurgTyp2 (same coding as SurgTyp1) (new variable)

SurgYr2 (same coding as SurgYr1) (new variable)

SurgRea2 (same coding as SurgRea1) (new variable)

SurgRep3 (same coding as SurgRea1) (new variable)

SurgTyp3 (same coding as SurgTyp1) (new variable)

SurgYr3 (same coding as SurgYr1) (new variable)

SurgRea3 (same coding as SurgRea1) (new variable)

SurgAb Any other abdominal surgery (besides what was already recorded)?
1= Yes, 2= No, 9= missing

BrImp Did the subject ever have breast implant(s)?
1= Yes, 2= No, 3=TRAM flap, 9= missing

BRIMPcomment open text (new variable)

BiopsyN Number of breast biopsies the subject had
0= none, #= number, 99= missing

PART 3: CANCER HISTORY
(This section will be repeated for second and third primary cancer occurrences, with all variables subsequently ending in a "2" and a "3" respectively.)

VARIABLE	DESCRIPTION (CODING SCHEME)
BreastCa	Ever have cancer of the breast? 1= Yes, 2= No, 9= missing
BCDAT1	Date of first primary cancer occurrence: MM/DD/YYYY, 00/00/0000=no diagnosis of cancer, 99/99/9999=missing
TYPB1	First Primary Breast Cancer Occurrence, coded as follows: DB=Invasive Ductal Breast Carcinoma DC=In Situ Ductal Breast Carcinoma MC=Medullary DBDC = Invasive and In Situ Carcinoma DBMC = Invasive Ductal Breast and Medullary DCMC = In Situ Ductal Breast and Medullary DBLB = Invasive Ductal and Invasive Lobular LB=Invasive Lobular Breast Carcinoma IV= Invasive breast cancer (unknown whether ductal or lobular) OB=Other Breast Carcinoma (for rare types) NO=none XX=missing

LCIS is not considered primary breast cancer occurrences.

BrCaUni1 Was the subject diagnosed with cancer in 1 or 2 breasts?
1= unilateral
2= bilateral
8= no cancer/ not applicable

9= Missing

BrCaLat1 Was it right or left breast?
1= left breast
2= right breast
3= both breasts
8= no cancer/ not applicable
9= missing

HISTB1 Histologic grade of the first primary breast cancer:
Look in the medical records to define histopathological grade.
~~X=Grade cannot be assessed~~
1=Well Differentiated
2=Moderately well Differentiated
3=Poorly differentiated
4=Undifferentiated
8=not applicable
9=missing, or grade could not be assessed

- TBC and MBC are usually recorded as TNM Stage - TXNXMX. Example is TIN0M0. TX gives the TNM Stage. MX gives the metastatic status.
- If TNM is not available, you can still look at the pathology records to define TBC and MBC. NBC can only be defined by medical records.

TBC1 TNM Stage (AJC) of breast cancer:
For all breast cancer subjects EXCEPT those who got cancer after prophylactic mastectomies.
0= DCIS
~~X=Primary tumor cannot be assessed~~
1=Tumor 2cm or less in greatest dimension
2=Tumor more than 2cm but less than 5 cm in greatest dimension
3=Tumor more than 5cm in greatest dimension
4=Tumor of any size with direct extension to chest wall or skin
5-7: ONLY FOR breast surgical subjects who later got cancer at surgical site:
5= Cancer occurrence in chest wall
6= Cancer occurrence in axilla
7= Distant cancer occurrence
8=Not applicable
9=missing, or primary tumor cannot be assessed

NBC1 Look in the medical records. Count all nodes and then the metastatic (positive) nodes. Nodal status of the first primary breast cancer: #positive nodes / #total nodes; 888=Not applicable, 999=missing. Examples are 0/10, 1/13.

NBCpos1 Nodal status of the first primary breast cancer. Count all positive nodes: # positive nodes; 88=Not applicable, 99=missing (new variable)

NBCtot1 Look in the medical records. Count all nodes examined. #total nodes; 88=Not applicable, 99=missing (new variable)

MBC1 Metastatic status of the first primary breast cancer. Look in the medical records.

0=no distant metastases
1=distant metastases
~~X=metastasis not assessed~~
8=Not applicable
9=missing or metastasis not assessed

MODB1 Primary mode of detection of the first primary breast cancer: Look in the medical records or doctors' notes/letters.

1=screening mammography
2=screening clinical breast exam
3=breast self-exam or visual detection by the subject
4=symptoms secondary to the cancer leading to detection by a physician
5=incidental finding at the time of prophylactic surgery
6=other incidental detection
7=other (specify)
8=Not applicable
9=missing

BrCaSu1 Did the subject have surgery as treatment for a first breast cancer? If cancer was found as part of a prophylactic surgery and no further surgery was performed, please indicate 2=NO

1= Yes, 2= No, 8= Not Applicable, 9= Missing/Unknown

BCSurgTyp1 Type of surgery for treatment of first breast cancer:

1= excisional biopsy,
2= lumpectomy
3= Unilateral mastectomy (type not specified)
3.1= Modified Radical Mastectomy(removal of breast, overlying skin and axillary lymph nodes)
3.2=QM=Subcutaneous Mastectomy (removal of breast with preservation of overlying skin)
3.3=RM=Radical Mastectomy (removal of breast, overlying skin, pector alis muscles and axillary contents)
3.4=SM=Simple (Total) Mastectomy (removal of breast and overlying skin)
3.5=OM=Other Mastectomy
4= bilateral mastectomy (4.1-4.5 same as above) (please use this only if bilateral breast cancer was diagnosed and both breasts were removed for breast cancer

treatmentm if a contralateral prophylactic mastectomy was performed, please record the prophylactic surgery in section 2.)
5=other (please specify)
8=NA
9=missing

BrCaSuYr1 In what year did the subject have surgery to treat first breast cancer?
YYYY, 0=no surgery; 9999=missing

BCSurgTyp12 same coding as SurgTyp1 (new variable)

BrCaSuYr12 same coding as BrCaSurgYr1 (new variable)

BCcomment open text (new variable)

ER1 What was the estrogen receptor status of the tumor?
1= ER positive, 2= ER negative, 3=Borderline, 8= Not Applicable, 9=Missing/Unknown

ERMethod1 What was the method used to determine ER status?
1= IHC, 2=Biochemical, 8= Not Applicable, 9=Missing/ Unknown

ERValue1 What is the value of the ER receptor: ##= Biochemical. ##% for IHC, 888= Not Applicable, 999=Missing/ Unknown

PR1 What was the progesterone receptor status of the tumor?
1= PR positive, 2= PR negative, 3=Borderline, 8= Not Applicable, 9=Missing/Unknown

PRMethod1 What was the method used to determine PR status?
1= IHC, 2=Biochemical, 8= Not Applicable, 9=Missing/ Unknown

PRValue1 What is the value of the PR receptor: ##= Biochemical. ##% for IHC, 888= Not Applicable, 999=Missing/ Unknown

Her2Neu1 What was the Her2-Neu status of the tumor?
1= Her2Neu positive, 2= Her2Neu negative, 8= Not Applicable, 9=Missing/Unknown

HerMethod1 What was the method used to determine Her2Neu status?
1= IHC, 2=FISH, 3=Borderline, 8= Not Applicable, 9=Missing/ Unknown

HerValue1 What is the value reported for Her2Neu:##= Value reported, 888= Not Applicable, 999=Missing/ Unknown

Her2Neu12 What was the Her2-Neu status of the tumor? (same coding as Her2Neu1) (new variable)

HerMethod12 What was the method used to determine Her2Neu status? (same coding as Her2Method1) (new variable)

HerValue12 What is the value reported for Her2Neu: (same coding as HerValue1) (new variable)

BCDAT2 Date of second primary breast cancer occurrence (same coding as BCDAT1)

TYPB2 Second Primary Breast Cancer Occurrence (same coding as TYPEB1)

BrCaUni2 Cancer in 1 or 2 breasts? (same coding as BrCaUni1)

BrCaLat2 Right or left breast, (same coding as BrCaLR1)

HISTB2 Histologic grade of the second primary breast cancer (same coding as HISTB1)

TBC2 TNM Stage (AJC) or in surgical subjects – the same coding as in TBC2

NBC2 Nodal status of the second primary breast cancer (same coding as NBC1)

NBCpos2 Positive nodal status of the second primary breast cancer. (same coding as NBCpos1) (new variable)

NBCtot2 All nodes examined.(same coding as NBCtot1) (new variable)

MBC2 Metastatic status of the second primary breast cancer (same coding as MBC1)

MODB2 Primary mode of detection of the second primary breast cancer (same coding as MODB1)

BrCaSu2 Did the subject have surgery as treatment for a second breast cancer (same coding as BrCaSu1)?

BCSurgTyp2 Type of surgery for treatment of second breast cancer (same coding as SyrgType1)

BrCaSuYr2 In what year did the subject have surgery to treat second breast cancer (same coding as BrCaSu1Yr)?

BCSurgTyp22 Type of second surgery for treatment of second breast cancer (same coding as SurgTyp1) **(new variable)**

BrCaSuYr22 In what year did the subject have second surgery to treat second breast cancer (same coding as BrCaSuYr1)? **(new variable)**

BCComment2 open text (new variable)

ER2 What was the estrogen receptor status of the second tumor? (same coding as ER1)

ERMethod2 What was the method used to determine ER status? (same coding as ERMethod1)

ERValue2 What is the value of the ER receptor (same coding as ERValue1)

PR2 What was the progesterone receptor status of the second tumor? (same coding as PR1)

PRMethod2 What was the method used to determine PR status? (same coding as PRMethod1)

PRValue2 What is the value of the PR receptor: (Same coding as PRValue1)

Her2Neu2 What was the Her2-Neu status of the tumor? (same coding as Her2-Neu1)

HerMethod2 What was the method used to determine Her-Neu status? (same coding as HerMethod1)

HerValue2 What is the value reported for Her_Neu: (same coding as HerValue2)

Her2Neu22 What was the Her2-Neu status of the tumor? (same coding as Her2Neu1) (new variable)

HerMethod22 What was the method used to determine Her2Neu status? (same coding as Her2Method1) (new variable)

HerValue22 What is the value reported for Her2Neu: (same coding as HerValue1) (new variable)

OvarianCa Ever have cancer of the ovaries?
1= Yes, 2= No, 9= missing

OCDAT1 Date of primary ovarian cancer occurrence: MM/DD/YYYY, 00/00/00 = no diagnosis of cancer, 99/99/9999=missing

TYPOV1 **TYPOV is very confusing, since typing of ovarian cancers seems non-standard. Most ovarian cancers are EO – epithelial carcinomas.**

First primary ovarian cancer occurrence coded as follows:

AP=Papillary Adenocarcinoma
EC = Endometroid Carcinoma
EO=Epithelial Ovarian Carcinoma or Adenocarcinoma of Ovary
FT= Fallopian Tube Carcinoma
GC=Granulosa Cell Type Carcinoma
PA=Peritoneal or Abdominal Carcinoma
PS=Papillary Serous Carcinoma
SC=Serous Carcinoma
OO=Other Ovarian Cancer
NO=none
XX=missing

HISTOV1 Histologic grade of the first primary ovarian cancer: X, 1-4; 8 and 9; Look at the medical records to assess histopathological grade of ovarian tumor.

~~X=Grade cannot be assessed~~
1=Well Differentiated
2=Moderately well Differentiated
3=Poorly differentiated
4=Undifferentiated
8=Not Applicable
9=Missing, or grade cannot be assessed

STGOV1 AJC Stage of the first primary ovarian cancer; X, 1-4, 8 and 9. ; Look at the medical records.

~~X=Primary tumor cannot be assessed~~
1=tumor limited to ovaries
2=tumor involves one or both ovaries with pelvic extension (uterus, tubes, or malignant cells in ascites or pertoneal washings)
3=tumor involves one or both ovaries with confirmed peritoneal metastasis outside the pelvis and/or regional lymph node metastasis
4=distant metastasis
8=Not Applicable
9=missing, or Primary tumor cannot be assessed

MODOV1 Primary mode of detection of the first primary ovarian cancer: 1-9; Look at the medical records or doctors' notes.

1=screening CA-125
2=screening vaginal ultrasound
3=screening clinical GYN exam
4=symptoms secondary to the cancer leading to the detection of the tumor by a physician
5=incidental finding at the time of prophylactic surgery
6=other (specify)

8=Not applicable
9=missing

OvSurg1 Did the subject have surgery to treat ovarian cancer?
1= Yes, 2= No, 8= Not Applicable (no cancer), 9= Missing

OvCaNo1 Number of ovaries removed to treat cancer
0= no ovaries removed
1= One removed
2= Both ovaries removed
8= Not applicable (no cancer)
9= Missing

OCcomment open text (new variable)

note: If subject has a second primary ovarian cancer, please record in other cancer section.

~~**OCDAT2** Date of second primary ovarian cancer occurrence (same coding as OCDAT1)~~

~~**TYPOV2** Second primary ovarian cancer occurrence (same coding as TYPOV1)~~

~~**HISTOV2** Histologic grade of the second primary ovarian cancer (same coding as HISTOV1)~~

~~**STGOV2** AJC stage of the second primary ovarian cancer (same coding as STGOV1)~~

~~**MODOV2** Primary mode of detection of the second primary ovarian cancer (same coding as MODOV1).~~

~~**OvSurg2** Did the subject have surgery to treat ovarian cancer (same coding as OvSurg)~~

~~**OvCaNo2** Number of ovaries removed to treat cancer (same coding as OvCaNo)~~

OtherCa Was the subject ever diagnosed with another type of cancer?
1= Yes, 2= No, 9= Unknown/ missing

OtCa1 Type of other cancer
0 None/ Not Applicable
1 Thyroid Cancer
2 Uterus
3 Basal Cell Carcinoma
4 Fallopian Tube
5 Melanoma
6 Skin (includes squamous)
7 Endometrial
8 Tongue
9 Stomach

10 Lung
11 Colon
12 Cervix
13 peritoneal
14 Omentum
15 Parotid gland
16 BRCA recurrence
17 Thyroid & Lung
18 Lymphoma
21 Leukemia
24 Renal
25 lung & esophagus & stomach
26 Bone metastases
27 Inguinal (lymph n.) metastasis
28 Esophagus
29 Mouth
30 Recurrent ovarian
31 Colon
32 Liver
33 Intestinal
34 Breast local metastasis
35 Breast metastasis to ovaries
36 Bone
37 Brain
38 Uterus & Endometrial
39 Vaginal
40 Bladder
41 Kidney
42 Hodgkin's Lymphoma
43 Sarcoma
44 LCIS
45 Non-Hodgkin's Lymphoma
46 pancreatic
47 nerve
48 PSU
49=Larynx
50=Breast Cancer= 3rd + Primary
51- Breast Metastasis, NOS
98 Multiple sites/ Other
99 Missing/ Unknown

OtCaYr1 Date of other cancer occurrence: YYYY, 0 = no diagnosis of cancer, 9999=missing

OtCa2 2nd cancer of other type, (same coding as OtCa1)

OtCaYr2 Date of second other cancer occurrence: YYYY, 0 = no diagnosis of cancer, 9999=missing

OTCAcomment open text (new variable)

PART 4: FOLLOW UP

VARIABLE	DESCRIPTION (CODING SCHEME)
VITAL	Latest Known Vital Status: 1=alive~~, no disease~~ ~~2=alive, had or has breast cancer~~

~~3=alive, had or has ovarian cancer~~
~~4=alive, had or has other cancer~~
5=dead, no cancer (never had cancer)
6=dead, from breast cancer
7=dead, from ovarian cancer
8=dead, from other cancer (not breast or ovarian)
9=dead, from other cause (but had cancer)
10=dead, from unknown cause
11= dead, from both breast and ovarian cancer
99=Unknown vital status (not known if patient is dead or alive)
~~**If the patient had breast cancer or ovarian cancer in the past, I usually record VITAL as 2 or 3, respectively, even if she is in remission or is cured.**~~

VITDATE Latest date for vital status: MM/DD/YYYY Required
What is last contact date (date of death, appointment with center, questionnaire date, date of last surgery)?

VITALComment open text (new variable)

PART 5: PEDIGREE

(NOTE: Count only the lineage from which the mutation came, or the side of the family with the predominant breast/ovarian cancer history. If possible, count only women over the age of 18. Do not count girls who died before the age of 18.)

VARIABLE	DESCRIPTION (CODING SCHEME)
NUM1	Number of female first degree relatives: ##, 99=missing
NUM1BC	Number of female first degree relatives with breast cancer: ##, 0=none, 99=missing
NUM1OV	Number of first degree relatives with ovarian cancer: ##, 0=none, 99=missing
NUM2	Number of female second degree relatives: ##, 99=missing
NUM2BC	Number of female second degree relatives with breast cancer: ##, 0=none, 99=missing
NUM2OV	Number of second degree relatives with ovarian cancer: ##, 0=none, 99=missing
MaleBC	Did any male relatives develop breast cancer? If yes, please list (ex: father, maternal uncle, brother etc…) open text (new variable)

PART 6: MUTATION CARRIER STATUS
A mutation is REQUIRED. If the subject does not have a BRCA1 or a BRCA2 mutation, her information should not be entered or used.

VARIABLE DESCRIPTION (CODING SCHEME)

Only carriers with deleterious *BRCA1/2* mutations are included in the study.

BRCA1 Does the subject carry a mutation in the BRCA1 gene?
1= yes, subject carries a mutation of known deleterious significance
2= yes, the subject carries a mutation, but it is of unknown significance
3= subject was tested and found to carry no BRCA1 mutation
4= unknown (not tested)
5= subject's carrier status must be rechecked or confirmed
6= obligate carrier
9= missing

BRCA1comment open text (new variable)

B1TYPE Actual BRCA1 mutation; 9999 if unknown or missing. Use BIC nomenclature.

B1Exon ##= exon number
0= N/A
99= missing

BRCA1NT nucleotide (new variable) cDNA nucleotide (nucleotide # in the transcript (cDNA) at which mutation occurs; Reference sequences: BRCA1 GenBank U14680; BRCA2 GenBank U43746)

BRCA1codon (new variable) **codon:** triplet codon # (ATG is +1) in which mutation occurs

BRCA1basechange (new variable) **base change** description of nucleotide difference compared to reference sequence

BRCA1AAchange (new variable) **amino acid change** description of resulting change in the encoded amino acid sequence

BRCA1MutationType (new variable) **mutation type**
F= Frameshift
IFI= In Frame Insertion
IFD= In Frame Deletion
IVS= Intervening Sequence
M= Missense
N= Nonsense

S=Splice
Syn= Synonymous
XX= Missin/ Unknown

BRCA1deleterious (new variable)
Yes, No, Unknown

B1test Manner in which BRCA1 testing was done
0= None/Not applicable
1=SSCP
2=SSCP+HD
3=CSGE
4=DHPLC
5=southern blot
6=protein truncation assay
7=full gene sequencing or CSGE
8=partial gene sequencing
9=Jewish panel
10=DNA chip array
11=other
12=single family mutation
99 = missing

BRCA2 Does the subject carry a mutation in the BRCA2 gene?
1=yes, subject carries a mutation of known significance
2=yes, the subject carries a mutation, but it is of unknown significance
3=subject carries no BRCA2 mutation
4=unknown (not tested)
5=subject's carrier status must be rechecked or confirmed
6=obligate carrier
9=missing

BRCA2comment open text (new variable)

B2TYPE Actual BRCA2 mutation; 9999 if unknown or missing. Use BIC nomenclature.

B2Exon ##= exon number
0= N/A
99= missing

BRCA2NT nucleotide (new variable) cDNA nucleotide (nucleotide # in the transcript (cDNA) at which mutation occurs; Reference sequences: BRCA1 GenBank U14680; BRCA2 GenBank U43746)

BRCA2codon (new variable) **codon:** triplet codon # (ATG is +1) in which mutation occurs

BRCA2basechange (new variable) **base change** description of nucleotide difference compared to reference sequence

BRCA2AAchange (new variable) **amino acid change** description of resulting change in the encoded amino acid sequence

BRCA2MutationType (new variable) **mutation type**

F= Frameshift
IFI= In Frame Insertion
IFD= In Frame Deletion
IVS= Intervening Sequence
M= Missense
N= Nonsense
S=Splice
Syn= Synonymous
XX= Missin/ Unknown

BRCA2deleterious (new variable)
Yes, No, Unknown

B2test Manner in which BRCA2 testing was done
0= None/Not applicable
1=SSCP
2=SSCP+HD
3=CSGE
4=DHPLC
5=southern blot
6=protein truncation assay
7=full gene sequencing or CSGE
8=partial gene sequencing
9=Jewish panel
10=DNA chip array
11=other
12=single family mutation
99 = missing

PART 7: REPRODUCTIVE HISTORY

VARIABLE	DESCRIPTION (CODING SCHEME)
AGEMEN	Age at menarche: ##, 99=missing
Preg	Was the subject ever pregnant? 1= Yes, 2= No, 9= missing

PAR Number of term pregnancies (live births, still births, and those that died less than 21 days following delivery): ##, 0=none, 99=missing

Abort Did the subject ever have an abortion?
0= no abortion, #= number of abortions, 99= missing

Still Did the subject ever have a still birth?
0= no still birth, #= number of still births, 99= missing

Miscarr Did the subject ever have a miscarriage?
0= no miscarriage, #= number of miscarriages, 99= missing

AGEFIRST Age at first term birth: ##, 0=never pregnant, 1=no term pregnancy, 99=missing

AGELAST Age at last term pregnancy: ##, 0=never pregnant, 1=no term pregnancies, 99=missing

PregYri, i=1,...,9 (year of ith pregnancy)
0000 no pregnancy, #### year of ith preg, 9999= missing

MedFert Did the subject ever take any medication for increased fertility?
1= Yes, 2= No, 9= missing

FertTx Did the subject ever receive treatment for fertility (IVF/ET) (does not include medication)?
1= Yes, 2= No, 9= missing

FertTyp1 What type of fertility treatment?
0= doesn't apply, 1= IVF, 2= Embryo transfer, 3= Super ovulation, 9=missing

FertTyp2 What type of fertility treatment (if more than one listed)? (new variable)
0= doesn't apply, 1= IVF, 2= Embryo transfer, 3= Super ovulation, 9=missing

Menopause Have the subjects periods stopped <u>completely</u> (if peri-menopausal record as 2=No for this question)?
1= Yes, 2= No, 9= missing

AGEMENO Age at menopause: ##, 0=pre-menopausal, 1=peri-menopausal, 99=unknown/missing

WHYMENO Under what circumstances did the subject undergo menopause?
1=natural menopause
2=surgical (hysterectomy and/or oophorectomy)

*2.1= Uterus removed only (5)
*2.2= Ovaries removed only (7)
*2.3= Uterus and ovaries removed (6)
3=as a result of cancer treatment (chemotherapy)
4=other (specify)

8=Not applicable

9=missing

MENOcomment open text (new variable)

PART 8: HEIGHT & WEIGHT

I use Conversion and Calculation website to convert from English system to metric: http://www.convertit.com/Go/ConvertIt/. I also printed out weight/height conversion sheets.

VARIABLE	DESCRIPTION (CODING SCHEME)
HT	Current height (in meters) of the subject: #.##, 9.99=missing
WT	Current weight (in kilograms) of the subject: ###.##, 999.99=missing
WT18	Weight of the subject at the age of 18: ###.##, 999.99=missing
***WT30**	Weight of the subject at age 30, same as WGT18.
***WT40**	Weight of the subject at age 40,same as WGT18.
***WTMax**	Heaviest weight ever of subject, same as WGT18

PART 9: LIFESTYLE FACTORS

VARIABLE	DESCRIPTION (CODING SCHEME)
BCP	Has the subject ever used birth control pills? 1=ever user, 2=never user, 9=missing
BCPBEG1	Age subject started using birth control pills: 888=not applicable, 999=missing.
BCPEND1	Age subject stopped using birth control pills: 888=still using or not applicable, 999=missing
TIBCP1	Longest period (in months) over which the patient used birth control pills: ###, 888=Not applicable, 999=missing
BCPBEG2	Age subject started using birth control pills for a second time: 888=not applicable, 999=missing.

BCPEND2 Age subject stopped using birth control pills for a second time: 888=still using or not applicable, 999=missing

TIBCP2 Longest period (in months) over which the patient used birth control pills for a second time: ###, 888=Not applicable, 999=missing

BCPtot Total duration (in months) of birth control pill/ oral contraceptive use
0= never used,# = years, 999 = missing

BCPnow Currently taking BCP's?
1= Yes, 2= No, 9= Missing

SMOK Has the subject smoked more than 100 cigarettes in her lifetime? 1=yes, 2=no, 9=missing

SMOKBEG Age subject started smoking: 888=not applicable, 999=missing.

SMOKEND Age subject stopped smoking: 888=still smoking or not applicable, 999=missing.

Packs Number of packs smoked per week
packs, 999= missing

PACKYR Number of pack years (1 pack year = smoke a pack [20 cigarettes/or 25 cigarettes in Canada] a day for an entire year or 365 packs/year): (###, 0=never a regular smoker, 999=missing

Suppose the person smokes 3 packs a week for 7 years. What is the packyear?

- (Packs per week x 52)/365 x number of years = # packyears. In this case, packyears = 3.
- Adjust for Canadian packs: (Canadian packs per week x 65)/365 x number of years = # packyears. For the Canadian who smokes 3 packs per week for 7 years, packyears = 3.7.

Coffee Did the subject ever drink coffee regularly?
1= Yes, 2= No, 99= missing

CofAgeF Age subject started regularly drinking coffee
age, 00= never drank coffee, 99= missing

CofAgeL Age subject stopped regularly drinking coffee
age (or current if still drink cf), 888= still drinking coffee, 0=never drank coffee, 99= missing

Cafeine No. of caffeinated cups (12 oz) consumed per day by subject
cups, 0=never drank coffee, 99= missing

Decaf No. of decaffeinated cups (12 oz) consumed per day by subject
cups, 0=never drank coffee , 99=missing

Total Ave. number of cups (12 oz) of coffee consumed per day
cups, 0=never drank coffee , 99=missing

DRINKNUM How many alcoholic drinks per week does the subject consume? 0=none, 1= 1-3, 2= 4-9, 3=10-12, 4= 13+, 9=missing
Suppose the person drinks socially or rarely, like once a month?

- I still put '1' if the person drinks occasionally or socially. '0' means total abstinence.

DrinkNum2 Average # of drinks per week
0 = NA (non-drinker or drinking status not stated) or "none"
1 = 0-3 drinks/week or
2 = 4-9 drinks/week
3 = 10-19 drinks/week
4 = 20+ drinks per week
5 = 1-3 drinks/week (GU - Modified Health History Questionnaire)
6 = 4-10 drinks/week (GU - Modified Health History Questionnaire)
7 = 11-17 drinks/week (GU - Modified Health History Questionnaire)
8 = 18-24 drinks/week (GU - Modified Health History Questionnaire)
9 = 25+ drinks/week(GU - Modified Health History Questionnaire)
99 = drinker, but drinks/week not stated or "missing"

Talc Did the subject ever used talcum powder regularly?
1= Yes, 2= No, 9=missing

TalcVag Did the subject apply it to the vaginal area?
1= Yes, 2= No, 9=missing

TalcSan Did the subject apply it to sanitary napkins?
1= Yes, 2= No, 9=missing

TalcOth Did the subject apply it anywhere else?
1= Yes, 2= No, 9=missing

TamTrial Is the subject a participant in the tamoxifen prevention trial?
1= Yes, 2= No, 9=Unknown/ Missing

Tamox # of years Tamoxifen used at time of survey (for Duke data, this was based on a follow-up survey done at a later date than the survey date recorded in the variable 'Adate')
0= never, 1= <1 year , 2= 1-2 years, 3= 3-5 years, 4= 6-10 years, 5= > 10 years, 9= missing duration (but did take tamoxifen) 99=unknown whether or not they took tamoxifen

TamoxComments open text (new variable)

PART 10: HORMONE REPLACEMENT THERAPY

VARIABLE	DESCRIPTION (CODING SCHEME)
HORM	Has the subject ever undertaken hormone replacement therapy? 1=ever, 2=never, 9=missing

Many patients take two or more kinds of HRT simultaneously. Record each kind separately.

HRTBEG1 In what year did the subject start using first HRT? YYYY, 0000=no use of HRT; 9999=missing

HRTEND1 What year did subject stop using first HRT? YYYY, 8888=Still using; 0000=Never used, 9999=Missing

HRTTOT1 Total months used, 9999=Missing

HRTWHY1 Why did the subject start using HRT?

1=Irregular menstrual bleeding
2=In order to delay menopause or change of life
3=Hot flashes/Night sweats/Vaginal dryness/Other symptoms of menopause
4=After a hysterectomy or after removal of ovaries
5=To treat or prevent bone loss or osteoporosis
6=To treat or prevent heart disease
7=To prevent miscarriage
8=Other (specify)
99=Don't Know/Missing
0=No HRT

HRWHAT1 Which hormones were replaced? 1=Estrogen; 2=Progesterone; 3=both estrogen & progesterone; 4=other (specify); 9=Don't know/Missing (5); 0=NA.

ESTTYP1 What was the estrogen supplement?

0=none

9=other (specify)
99=Don't Know/Missing

1=Premarin
2=Ogen
3=Estrace
4=Estraderm
5=Ortho-est
6=Estratest
7=Estratab
8=CombiPatch

10=Estriol
11=Tri-Est
12=Estring
13=Estrogel

19=Progynova
20=Promensil
21=Zumenon

Other Transdermals
61=Climara
62=Vivelle
63=Alora
64=FemPatch
65=Esclim
66=Evorel
67=Estracomb
68=Systen

Estrogen+Androgen
80=Premarin+methyl-testosterone

Estrogen-Progesterone Combinations
101=FemHRT
102=Ortho-Prefest
103=Prempro
104=Premphase
105=Femoston
106=Kliogest
107=Livial/Tibolone
108=Zumeston
109=Climene
110=Activella
111=Premelle 5/Cycle

Contraceptives
200=Mercilon
201=Mirena IUD
202=Microgynon 30

14=Gynodian		203=Trigynon
15=Orthogynest	**Selective Estrogen**	204=Ortho777
16=Gynodian	**Modulator**	205=MinEstrin
17=Cenestin	90=Raloxifene	206=Orgametril
18=Synapause	91=Evista	207=Loestril

PROGTYP1 What was the brand name of the progesterone supplement?

0=none	**Other medroxyprog. acetate brands**	**Estrogen-Progesterone Combinations**
9=other (specify)	10=Cycrin	101=FemHRT
99=Don't Know/Missing	11=Amen	102=Ortho-Prefest
	12=Curretab	103=Prempro
1=Provera	13=Crinone	104=Premphase
2=Prometrium		105=Femoston
3=Micronor		106=Kliogest
4=Aygestin	**Other Norethindrones**	107=Livial/Tibolone
5=Norlutate	14=Nortulin	108=Zumeston
6=Overette	15=NorQD	109=Climene
		110=Activella
	16=Megace	111=Premelle 5/Cycle
	17=Utrogestan	
	18=Norlutate	**Contraceptive**
	19=Orgametril	250=Depo-Provera
	20=Duphaston	

additional HRT- list under 9-Other:

Arogest (Israel)
Natural product
Climonorm
depoestradiol
Genavit
Testosterone
Orthogynest
ogen
g-estropipate
Natural progesterone cream
Progestin
estradiol
Premaril
EstraTabs
Diastrabestrol
Progenin C (israel)

HRMODE1 What was the form of the hormone replacement therapy?

1=Pill
2=Patch
3=Shot
4=Cream
5=Suppository/Vaginal Ring
99=Don’t Know/Missing
0=none

HRSTOP1 If the subject stopped taking HRT, why did she stop?

1=Subject had complications and side effects
2=Subject was afraid of harmful effects
3=Subject no longer needed it
4=HRT was too expensive or no longer available
5=Subject became ill
6=Subject became pregnant
7=Subject needed a different brand or dosage
8=The doctor recommended termination of HRT
9=HRT did not work
10= Other reason
66=Currently using this medication
99=Don't know/Missing
0=NA

HRTBEG2 In what year did the subject start using another form of HRT?

HRTEND2 When did subject stop using the second form of HRT?

HRTOT2 Total months of use.

HRTWHY2 Why did the subject start using HRT again?

HRWHAT2 Which hormones were replaced?

ESTTYP2 What was the brand name of estrogen supplement?

PROGTYP2 What was the brand name of the progesterone supplement?

HRMODE2 What was the form of the hormone replacement therapy?

HRSTOP2 If the subject stopped taking this HRT, why did she stop?

HRTcomment open text (new variable)

AdditionalComment open text (new variable)

These are optional fields. These codes do not have to be filled.

PART 11: MEDICAL RECORDS

VARIABLE	DESCRIPTION (CODING SCHEME)
PATH1	Pathology from the first prophylactic surgery: 1=yes, 2=no, 3=no prophylactic surgery, 9=missing
IMAGE1	Imaging reports prior to the first prophylactic surgery: 1=yes, 2=no, 3=no prophylactic surgery, 9=missing
PATH2	Pathology from the second prophylactic surgery: 1=yes, 2=no, 3=no prophylactic second surgery, 9=missing
IMAGE2	Imaging reports prior to the second prophylactic surgery: 1=yes, 2=no, 3=no second prophylactic surgery, 9=missing
CPATH1	Pathology from the first primary cancer biopsy and/or surgically resected tumor: 1=yes, 2=no, 3=no cancer, 9=missing
CIMAGE1	Imaging reports from the first primary cancer occurrence: 1=yes, 2=no, 3=no cancer, 9=missing
CPATH2	Pathology from the second primary cancer biopsy and/or surgically resected tumor: 1=yes, 2=no, 3=no second cancer, 9=missing
CIMAGE2	Imaging reports from the second primary cancer occurrence: 1=yes, 2=no, 3=no second cancer, 9=missing
CPATH3	Pathology from the third primary cancer biopsy and/or surgically resected tumor: 1=yes, 2=no, 3=no third cancer, 9=missing
CIMAGE3	Imaging reports from the third primary cancer occurrence: 1=yes, 2=no, 3=no third cancer, 9=missing

Cancer Treatment Information:

TYPOTH1	Type of other cancer: 1=stomach, 2=pancreatic, 3=thyroid, 4=leukemia, 5=Hodgkin's lymphoma, 6=colon, 7=other in-situ carcinomas (specify), 8=other invasive carcinoma (specify), 9=none, 99=missing
TRT1	Was a treatment regimen pursued by the subject for her first primary? 1=yes, 2=no, 8= not applicable 9=missing
HORM1	Was hormonal therapy part of this treatment? 1=yes (specify type and dosage. If these specifics are not available, then leave this note field blank), 2=no, 8= not applicable 9=missing
CHEM1	Was chemotherapy part of this treatment? 1=yes (specify type and dosage), 2=no, 8 = not applicable 9=missing
RAD1	Was radiation therapy part of this treatment? 1=yes (specify type and dosage), 2=no, 8= not applicable, 9=missing
SURG1	Was surgery part of this treatment? 1=yes (specify type(s)), 2=no, 8= not applicable, 9=missing
BREC1	If the first primary was breast cancer, was breast reconstruction undertaken? 1=yes, 2=no, 8= not applicable, 9=missing
OTRT1	Was another treatment elected? 1=yes (specify), 2=no, 8= not applicable, 9=missing
DATSTR1	Date therapy commenced: MM/DD/YYYY, 99/99/9999=missing (again, if only the year

is known, enter as “99/99/YYYY”) 00/00/00 = not applicable

DATSTP1 Date therapy ended: MM/DD/YYYY, 99/99/9999=missing 00/00/00= not applicable

DATRCR1 Date of first post-treatment recurrence: MM/DD/YYYY, 00/00/00=no recurrence 99/99/9999=missing

SITRCR1 Site of first recurrence: 1=local, 2=regional, 3=distant, 8=Not applicable, 9=missing

DATRCR1 Date of second post-treatment recurrence: MM/DD/YYYY, 00/00/00=no second recurrence, 99/99/9999=missing

SITRCR1 Site of second post-treatment recurrence: 1=local, 2=regional, 3=distant, 8=Not applicable, 9=missing

DATRCR1 Date of third post-treatment recurrence: MM/DD/YYYY, 00/00/00=no third recurrence, 99/99/9999=missing

SITRCR1 Site of third post-treatment recurrence: 1=local, 2=regional, 3=distant, 8=Not applicable, 9=missing