

Name: «FNAME» «LNAME»	AGE: «SUBJECT_CURRENT_AGE»
Address: «ADDR1» «ADDR2» «CITY» «STATE» «ZIP»	In-home interview date: «NURSE_VISIT_DATE» Eligibility date: «CCR_FIRST_ELIG_DATE»
1st Phone #: «PHONE1»	DOB: «DOB»
2nd Phone #: «PHONE2»	Email: «EMAIL_ADDR»

COMMENTS: «SUBJECT_ADDR_COMMENTS»; «SUBJECT_COMMENTS»

Call #	Initials	Date	Time	*Result	Comments
1.			____:____ AM / PM		
2.			____:____ AM / PM		
3.			____:____ AM / PM		
4.			____:____ AM / PM		
5.			____:____ AM / PM		
6.			____:____ AM / PM		
7.			____:____ AM / PM		
8.			____:____ AM / PM		
9.			____:____ AM / PM		
10.			____:____ AM / PM		
11.			____:____ AM / PM		
12.			____:____ AM / PM		
13.			____:____ AM / PM		

*Results: NA=No Ans.; NH=Not Home; LVM=Left Voice Mail; CB=Call Back; R=Refused; NFC=No Further Contact; CC=Call Completed

NOTES:

CBCS3 Follow Up #9 (9-Year) Telephone Survey

Name: «FNAME» «LNAME»	Collected by (your initials):
DOB: «DOB» AGE: «SUBJECT_CURRENT_AGE»	Date collected: ___ ___ / ___ ___ / ___ ___
Date of Elig: «CCR_FIRST_ELIG_DATE»	Start time: ___ ___ : ___ ___ am / pm

READ: Thank you for agreeing to talk with me about your breast cancer experience. All of the information you share with me today will be kept confidential, and it should only take about 15 to 20 minutes. You do not have to answer any questions that you don't want to answer. Just let us know if you want to skip a particular question and we'll move on to the next question. We'll also send you a check for \$10 within 4 weeks of completing this call. Do you have any questions before we begin?

VERIFY PARTICIPANT'S ADDRESS/CONTACT INFO:

READ: Before we begin, please let me double-check your address and phone number. (Review/update address and telephone contact info printed on call log.)

(Okay, let's get started!) How are you doing? How is your general health? (Don't record answer, take notes if needed)

READ: The last time we talked, we reviewed your breast cancer treatment history. I'd like to go over that with you now in order to update your treatment information. (See HP sheet. Review for information about previous recurrences/2nd primaries. Note whether addl. Med. Recs. are still needed from previous contacts.)

1. Since we last spoke (or within the last 2 years), have you had a (or another) **recurrence** of your breast cancer? This means the breast cancer has come back in the same place or it has spread from the original tumor to another part of your body.

1 ___ YES 2 ___ NO (Skip to Q. 2) 9 ___ NA or Don't Know (Skip to Q. 2)

1a. When was the recurrence? _____

1b. In what part of your body? _____

1c. How were you diagnosed? (**Read options**, check all that apply)

a ___ Blood test

b ___ Biopsy or surgery (complete boxes below for all surgical procedures for recurrence)

c ___ Imaging (ultrasound, pet scan, cat scan, x-ray)

d ___ Other: _____

Please tell me about any surgical procedures you have had for this recurrence.

1st Surgical Procedure for recurrence:

SCHEDULED or **ACTUAL** Surgical Procedure DATE: _____
(Circle "Scheduled" or "Actual" above)

Procedure type(s): _____

Facility/Clinic Name/Address: _____

Doctor Name/Address: _____

COMMENTS: _____

Did you have another surgical procedure for the recurrence, or do you have any procedures scheduled? Y N

2nd Surgical Procedure for recurrence

SCHEDULED or **ACTUAL** Surgical Procedure DATE: _____
(Circle "Scheduled" or "Actual" above)

Procedure type(s): _____

Facility/Clinic Name/Address: _____

Doctor Name/Address: _____

COMMENTS: _____

1d. Have you received any other types of treatment for the recurrence? 1___YES 2___NO (skip to Q.2)

1st other Treatment/Procedure type(s) for recurrence: _____

1st Treatment or Procedure start date: _____

Is treatment completed or ongoing or stopped?

1___COMPLETED 2___ONGOING 3___STOPPED BEFORE IT WAS COMPLETED

If completed or stopped: COMPLETION/STOP DATE: _____

Doctor Name: _____

MD/Facility/Clinic Name: _____

Address: _____

City: _____ State: _____ Zip: _____

COMMENTS: _____

2nd other Treatment/Procedure type(s) for recurrence: _____

2nd Treatment or Procedure start date: _____

Is treatment completed or ongoing or stopped?

1___COMPLETED 2___ONGOING 3___STOPPED BEFORE IT WAS COMPLETED

If completed or stopped: COMPLETION/STOP DATE: _____

Doctor Name: _____

MD/Facility/Clinic Name: _____

Address: _____

City: _____ State: _____ Zip: _____

COMMENTS: _____

2. Since we last spoke (or within the last 2 years), have you been diagnosed with a (or another) **new breast tumor**? This means you had a new breast tumor in a new area on the same breast or in the other breast—some people call this a second primary.

1___YES 2___NO (Skip to Q. 3) 9___NA or Don't Know (Skip to Q. 3)

2a. When were you diagnosed with the new breast tumor? _____

2b. Was it in the same breast or the other breast? _____

2c. How were you diagnosed? (**Read options**, check all that apply)

a_____Blood test

b_____Biopsy or surgery (complete box(es) below for all surgical procedures for new primary)

c_____Imaging (ultrasound, pet scan, cat scan, x-ray)

d_____Other: _____

Please tell me about any surgical procedures you have had for this new tumor.

1st Surgical Procedure for new breast primary
SCHEDULED or **ACTUAL** Surgical Procedure DATE: _____
 (Circle "Scheduled" or "Actual" above)

Procedure type(s): _____

Facility/Clinic Name/Address: _____

Doctor Name/Address: _____

COMMENTS: _____

Did you have another surgical procedure for the new tumor, or do you have any procedures scheduled? Y N

2nd Surgical Procedure for new breast primary
SCHEDULED or **ACTUAL** Surgical Procedure DATE: _____
 (Circle "Scheduled" or "Actual" above)

Procedure type(s): _____

Facility/Clinic Name/Address: _____

Doctor Name/Address: _____

COMMENTS: _____

2d. Have you received any other types of treatment for the new tumor? 1___YES 2___NO
 (skip to Q.3)

1st other Treatment/Procedure type(s) for new tumor: _____

Treatment or Procedure start date: _____

Is treatment completed or ongoing or stopped?

1___COMPLETED 2___ONGOING 3___STOPPED BEFORE IT WAS COMPLETED

If completed or stopped: COMPLETION/STOP DATE: _____

Doctor Name: _____

MD/Facility/Clinic Name: _____

Address: _____

City: _____ State: _____ Zip: _____

COMMENTS: _____

2nd other Treatment/Procedure type(s) for new breast primary: _____

2nd Treatment or Procedure start date: _____

Is treatment completed or ongoing or stopped?

1___COMPLETED 2___ONGOING 3___STOPPED BEFORE IT WAS COMPLETED

If completed or stopped: COMPLETION/STOP DATE: _____

Doctor Name: _____

MD/Facility/Clinic Name: _____

Address: _____

City: _____ State: _____ Zip: _____

COMMENTS: _____

3. (If YES to Q. 1- recurrence or Q. 2 - new breast primary). With your permission, we may want to request copies of your medical records from the doctors and hospitals you mentioned and request samples of the diagnostic surgeries or procedures for your (recurrence or new breast primary) to compare with the tissue we have from your original diagnosis. We'd like to mail the consent forms to you along with a pre-paid business reply envelope. If you sign the forms and mail them, we'll send you an additional check for **\$15**. It's okay if you choose not to give us permission to get copies of your medical records - you can still participate in the study.

May I send the consent forms to you for your signature? 1___YES 2___NO

(If **YES**, circle YES on checklist (last page of survey) next to "Medical Records/Tumor block consents.")

4. In the past two years, have you been told by a doctor that you had cancer in a place other than your breasts? (If possible, verify that this is for a new cancer, and not for a recurrence or metastasis. If recur or metastasis, record treatment info in questions 1-2.)

1___YES 2___NO (Skip to Q. 6a) 9___NA or Don't Know (Skip to Q. 6a)

5.	a. What type of cancer did you have?	b. What year was this cancer diagnosed?
1 st Diagnosis		
2 nd Diagnosis		
3 rd Diagnosis		

(9999 if don't know)

(Note re: data entry: If other cancer is reported, please record type and date in a FU#9 HP tab. Update to "MR not needed.")

6a. (Review HP Form with participant and provide an update with latest treatment information.)

Ask: Since the last time we spoke, are there any other health care providers (physician, clinic, hospital, etc.) who treated you or followed up with you, or whom you are scheduled to see, for follow-ups, treatment or surgery related to breast cancer? This may include follow-up office visits with your surgeon or plastic surgeon, oncologist or doctor, radiation oncologist, primary care physician, including procedures or treatments for your initial diagnosis.

1___YES 2___NO (If NO Skip to Q. 7)

1st New Visit/other Treatment or Procedure not previously listed on HP Report

SCHEDULED or **ACTUAL** Treatment/Visit Date: _____
(Circle "Scheduled" or "Actual" above)

Purpose of Visit: _____

If Follow-up or annual visit, ask: Was this a routine follow-up, or did the doctor address a specific health issue or problem you were having? ___Routine Visit ___Problem

(Specify, if problem): _____

Treatment for: ___Initial Diagnosis

Facility/Clinic Name/Address: _____

(Ordering) Doctor Name/Address: _____

Doctor/Facility Tel. _____

COMMENTS: _____

6b. Have you had any additional cancer related visits, treatments or procedures not already mentioned?

1___YES 2___NO (If NO Skip to Q. 7)

2nd New Visit/Other Treatment or Procedure not previously listed on HP Report

SCHEDULED or **ACTUAL** Treatment/Visit Date: _____
(Circle "Scheduled" or "Actual" above)

Purpose of Visit: _____

If Follow-up or annual visit, ask: Was this a routine follow-up, or did the doctor address a specific health issue or problem you were having? ___Routine Visit ___Problem

(Specify, if problem): _____

Treatment for: ___Initial Diagnosis

Facility/Clinic Name/Address: _____

(Ordering) Doctor Name/Address: _____

Doctor/Facility Tel. _____

COMMENTS: _____

6c. Have you had any additional cancer-related visits, treatments or procedures not already mentioned?

1___ YES 2___ NO (If NO Skip to Q. 7)

3rd Visit/Treatment or Procedure not previously listed on HP Report

SCHEDULED or **ACTUAL** Treatment/Visit Date: _____
(Circle "Scheduled" or "Actual" above)

Purpose of Visit: _____

If Follow-up or annual visit, ask: Was this a routine follow-up, or did the doctor address a specific health issue or problem you were having? ___Routine Visit ___Problem

(Specify, if problem): _____

Treatment for: ___Initial Diagnosis

Facility/Clinic Name/Address: _____

(Ordering) Doctor Name/Address: _____

Doctor/Facility Tel. _____

COMMENTS: _____

7. (If YES to new visits/treatments/procedures for breast cancer). With your permission, we may want to request copies of your medical records from the doctors and hospitals you mentioned. We'd like to mail the consent forms to you along with a pre-paid business reply envelope. If you sign the forms and mail them, we'll send you a check for **\$15**. It's okay if you choose not to give us permission to get copies of your medical records - you can still participate in the study.

May I send the consent forms to you for your signature? 1___ YES 2___ NO

(If **YES**, circle YES on checklist (last page of survey) next to "Medical Records consents only.")

READ: Now I'd like to ask you about any new medical conditions other than cancer that you may have, that is, any new health issues that you had **for the first time in the past two years**. (Note: Answers re: health conditions from FU6 and FU7 are included in folder.)

8. In the past two years, have you been told by a doctor or other health professional that you have a new medical condition?

1___ YES 2___ NO (Skip to Q. 10) 9___ NA or Don't Know (Skip to Q. 10)

IF YES: 9a. What medical condition were you diagnosed with? (If they don't know what a medical condition is, read list: Alzheimer's, arthritis, asthma COPD, diabetes, HIV/AIDs, hypertension, kidney failure, cirrhosis or liver disease, osteoporosis, inflammatory bowel disease, ulcer, anxiety, depression, bipolar disorder, schizophrenia, congestive heart failure, angina/chest pain, heart attack, high cholesterol, stroke, blood clots in leg or lungs, thyroid problem)	b. What year was this condition diagnosed?	c. Do you currently take any prescription medications for this condition?
1st new medical condition: (describe)	(DK: 9999)	1 ___ Yes 2 ___ No
2nd new medical condition: (describe)	_(DK: 9999)	1 ___ Yes 2 ___ No
3 rd new medical condition: (describe)	(DK: 9999)	1 ___ Yes 2 ___ No
4 th new medical condition: (describe)	(DK: 9999)	1 ___ Yes 2 ___ No

READ: Next, I want to ask some questions about your **lifestyle**.

10. How much do you currently weigh? _____ lbs. (enter 888 if don't know or NA)

11. Have you gained or lost more than 5 pounds in the past two years?

1 ___ YES 2 ___ NO (Skip to Q. 12) 9 ___ Don't Know (Skip to Q. 12)

11a. ___ Gained: How much? _____ lbs.

11b. ___ Lost: How much? _____ lbs.

12. Do you currently smoke?

1 ___ YES 2 ___ NO (Skip to Q. 13) 9 ___ NA or UNK (Skip to Q. 13)

12a. On average, how many cigarettes do you smoke per day? (20 cigs/pk)

1 ___ More than 2 packs

2 ___ >1½ to 2 packs

3 ___ >1 to 1½ pack

4 ___ ½ to 1 pack

5 ___ Less than ½ pack

6 ___ Once in a while, not every day

9 ___ NA

13. Do you currently drink alcoholic beverages?

1___YES 2___NO (Skip to Q. 14) 9___NA (Skip to Q. 14)

13a. On average, how many drinks containing alcohol do you have each **week**? By one drink, we mean, for example, a 12 ounce can or glass of beer or cooler, a 5 ounce glass of wine, or a drink containing 1 shot of liquor.

_____ drinks per week
(Enter "000" if less than 1 drink per week)

READ: Now I am going to ask you a few questions about your physical activity since we last spoke to you. I am going to ask about moderate and vigorous physical activity.

14. **Moderate activities cause your heart rate and your breathing to go up just a little bit.**

How many days per week do you do moderate physical activity for at least 10 minutes at a time?

_____ Days per week (enter 9 for Not Answered or Unknown)

15. **Vigorous activities cause a large increase in your heart rate and breathing rate.**

How many days per week do you do vigorous physical activity for at least 10 minutes at a time?

_____ Days per week (enter 9 for Not Answered or Unknown)

16. What type of health insurance do you have **now**? (Read options, check all that apply)

- a_____ None
- b_____ Private health insurance purchased on your own or by your husband or partner
- c_____ Private health insurance from your employer or workplace or that of your husband or partner
- d_____ Medicaid
- e_____ Medicare
- f_____ Any other insurance that covers part of your medical bills
- g_____ Not Answered or Unknown

17. **In the past two years**, was there a time when you did not have any health insurance?

1___YES 2___NO (Skip to Q. 18) 9___NA or Unknown (Skip to Q. 18)

17a. Combining all of the times that you were without coverage **in the past two years**, what was the total amount of time that you did not have health insurance? (ENTER years and months, enter 00 if none, enter 99 if Unknown)

_____ Years _____ Months

18. **In the past two years**, was there ever a time that you wanted to see a doctor, but could not because of financial issues?

1___YES 2___NO 9___NA or Unknown

19. In the past two years, was there ever a time that you wanted to see a doctor, but could not, because of transportation issues?

1__YES 2__NO 9__ NA or Unknown

READ: Now I'd like to ask a few questions about some things that may have affected your quality of life **when you were first diagnosed with breast cancer.**

20. When you were first diagnosed and being treated for breast cancer, were you caring for your children, grandchildren, spouse or partner, parents, relative, or someone else? (Put an "X" in front of all that apply:

- a. ____ NO (If No, Skip to Q. 22)
- b. ____ Children
- c. ____ Grandchildren
- d. ____ Spouse/partner
- e. ____ Parent(s)/relative/someone else

21. Was there ever a time during your breast cancer treatment that you wanted to see your doctor or go to an appointment but could not, because of child care or elder care (or family care) issues?

1__YES 2__NO

22. When you were first diagnosed, did your doctor or nurse offer to refer you to an individual or family counselor to discuss how your diagnosis and treatment could impact you and your family?

1__YES 2__NO 9__ N/A or Don't know

23. When you were first diagnosed, did you talk to your children, spouse or partner, or parents, or immediate family members about your diagnosis and treatment and how it would impact the family?

- a. Children: 1__YES 2__NO 9__ N/A or Don't know
- b. Spouse/partner: 1__YES 2__NO 9__ N/A or Don't know
- c. Parents/family members: 1__YES 2__NO 9__ N/A or Don't know

READ: Did you, or did your children, spouse, parents or members of your immediate family, ever participate in any of the following to help cope with your breast cancer? (Place an “X” in box under correct column for all that apply).

	24. Participant	24. Co de	25. Child(ren)	25. Co de	26. Spouse/ partner or family member	26. Co de
a. Support group						
b. Professional counseling						
c. Talk to religious leaders or members of your spiritual community						
d. Talk to doctors, nurses, or other health professionals						
e. Talk to family						
f. Talk to friends						
g. Yoga						
h. Meditation						
i. Stress reduction or management techniques						
j. Other: Please specify: _____						
k. Other: Please specify: _____						

27. (If Yes to any answers in Q24-Q26): Overall, how easy or difficult was it for you to identify the resources you needed in order to get the help you wanted for yourself, your children, or your spouse?

- 1 ____ Very easy
- 2 ____ Somewhat easy
- 3 ____ Somewhat difficult
- 4 ____ Very difficult

Thank you for answering the questions in this survey.

28. We would like your permission to contact you again in another year or so, just to see how you're doing. Is that okay with you?

1__YES 2__NO (Note any reason mentioned for no further contact below, then Skip to Q. 29. **NOTE: update CBCS database "May Contact" field to "NO"**)

If **NO**, comments/reason: _____

IF YES, COMPLETE CONSENT ADDENDUM

Read: The last thing I need to do is to read a short consent addendum to you.

(READ CONSENT ADDENDUM VERBATIM, CHECK APPROPRIATE ANSWERS, SIGN/DATE FORM. It is fine to summarize or explain the options on the consent addendum AFTER reading the entire form to the participant.)

(Note: Must include a signed copy of consent addendum in mailing – Circle YES in checklist box on last page of survey YES on checklist (last page of survey) next to "Consent Addendum")

OTHER CONTACTS

(Review Q.29 If Consent Addendum indicates YES to contacting other contacts. If NO, Go to Q. 30.)

29. **VERIFY OTHER CONTACT INFO: READ:** In case we can't reach you, is there a name and phone number you can give us for a friend or relative who may be able to help us find you? **(VERIFY OTHER CONTACT INFO from printouts, update database if needed).**

1__YES 2__NO (Go to Q. 30)

(If Yes) 1st contact:

Name: _____ Relationship: _____

Address: _____

Phone number(s): _____ E-Mail address: _____

Is there a 2nd contact?

Name: _____ Relationship: _____

Address: _____

Phone number(s): _____ E-Mail address: _____

30. Do you have any questions or comments, before we end? 1__YES 2__NO

(Answer general questions about the study only. For medical questions, refer them to their MD.)

READ: That's it! Thank you for completing this call. You should be receiving a mailing from us within 4 weeks, including a check for **\$10** to thank you for taking the time to complete this follow up call with us.

CHECKLIST FOR MAILING (REVIEW WITH STUDY PARTICIPANT)		
(If YES to any other items below, please mention that they may be in the mailing, as well as business reply envelope.)		
Consent Addendum (1 copy "FOR YOUR RECORDS")	YES	NO
Medical records consents only (no block consents) (2 copies)	YES	NO
Medical records/Tumor block consents (2 copies)	YES	NO
New consent form for additional tissue specimen (2 copies)	YES	NO
Other? _____	YES	NO

ENDING: Thank you so much for all your help with the Carolina Breast Cancer Study. Please contact us any time, we always look forward to speaking with you. Our toll-free number is 1-866-927-6920, and my name is _____. On behalf of the Carolina Breast Cancer Study, we wish you all the best.

Interview Call End time: ____ ____ : ____ ____ **am / pm**

Notes:

University of North Carolina-Chapel Hill**Consent to Participate in a Research Study****Addendum to provide additional information to subject after original consent****IRB Study #92-0410****Consent Form Version Date:** October 26, 2018**Title of Study:** LCCC 9204: Population-Based Molecular Epidemiology of Breast Cancer: “The Carolina Breast Cancer Study”**Principal Investigator:** Melissa Troester, PhD, Dept. of Epidemiology (919) 966-7424; troester@unc.edu**Study Contact:** Mary Beth Bell, Project Manager (919) 966-9438; email mbell@unc.edu

The following information should be read as an addition to the original Consent Form that you read and signed at the beginning of the study. Unless specifically stated otherwise in the following paragraphs, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate, or may withdraw your consent to participate at any time, for any reason. A copy of this consent addendum will be provided to you by mail.

New or additional information**Consent Addendum**

In the event we are unable to reach you for future contact at the telephone number, address, or email on file for you, we may attempt to find updated contact information for you by calling the people you have provided as “other contacts.” We may also contact the health care providers that we have on file for you to ask for updated contact information. We may also try to find updated contact information that is available publicly on the internet, such as Yahoo or Google.

We will always maintain your privacy and confidentiality during any contact attempts. We will say only that we are trying to reach you about a UNC health study. We will ask to speak with you directly. If you are no longer affiliated with that number, we will request your updated contact information. We will never identify the Carolina Breast Cancer Study by name or indicate that you are enrolled in the Carolina Breast Cancer Study. We will never mail any study materials to an address other than the one you, your other contacts, your physician, or the post office provides to us.

Subject’s Agreement:

The information contained in the consent addendum has been read to me, and I may contact the study personnel listed on this consent addendum if I have any questions or concerns. If necessary, in order to obtain updated contact information for me in the future, I voluntarily allow study staff to contact:

My “other contacts:” **YES** **NO**My health care providers: **YES** **NO**My place of work: **YES** **NO**_____
Signature of Staff Person Reading Consent Addendum_____
Date_____
«FNAME» «LNAME»**Printed Name of Research Subject**

