NSABP Protocol B-32
Quality of Life Questionnaire

INSTRUCTIONS TO PARTICIPATING CCOP INSTITUTION

This form applies to all patients at your institution enrolled in B-32, except those who have been diagnosed as sentinel node positive, or have had a documented breast cancer recurrence or a second primary cancer. The first page is to be completed by NSABP CCOP personnel. Fill in the items listed on this page, print the first 3 letters of the patient's last name and the patient's study ID at the top of pages 2, 3, 4 & 5 and give the questionnaire to the patient for completion. After the patient has completed the questionnaire, verify that the date has been recorded at the top of page 2, and submit the completed questionnaire to the NSABP Biostatistical Center. If all efforts to administer the scheduled QOL fail, a QMD form should be submitted instead.

***At Baseline*: The baseline questionnaire must be administered after the consent form has been signed but before the patient has had her sentinel node surgery.** *Please administer it during the office visit or over the phone immediately after the office visit.*
***At 1 Week and 2-3 Weeks Post-Op., 6, 12, 18, 24, 30 and 36 months*:** *At the one-week visit, please administer it during the office visit or over the phone immediately after the office visit. For the 2-3 weeks post-op visit and subsequent visits, please administer it during the office visit. If that is not possible, administer the form by mail or over the phone soon after the visit.*

First Three Letters of Patient's Last Name ☐☐☐ (1-3)

Patient Study ID 7 2 ☐☐☐☐☐☐☐ (4-12)

Institution Name/Affiliate Name________________/________________

Person Completing Form ____________ ____________ ____________
Last Name First Name Phone

Are data amended? ☐ (13) 1 - Yes 2 - No (If yes, circle amended items in red.)

Time Point for this Questionnaire (Check one) (14)

(0) __ **Baseline** (All patients)
(1) __ **1 week post-op** (Sentinel node negative patients only)
(2) __ **2-3 weeks post-op** (Sentinel node negative patients only)
(3) __ **6 month follow-up** (Sentinel node negative patients only)
(4) __ **12 month follow-up** (Sentinel node negative patients only)
(5) __ **18 month follow-up** (Sentinel node negative patients only)
(6) __ **24 month follow-up** (Sentinel node negative patients only)
(7) __ **30 month follow-up** (Sentinel node negative patients only)
(8) __ **36 month follow-up** (Sentinel node negative patients only)

This form is being filled out: ☐ (15)
0 - By patient in office
1 - By clinical staff on phone with patient
2 - By patient, mailed to office

Most extensive breast surgery to date ☐ (16)
1 - Excisional biopsy/lumpectomy
2 - Total mastectomy
3 - Neither (only FNA or core biopsy to date)

Side of the most extensive breast surgery ☐ (17)
1 - Right
2 - Left
3 - Bilateral

Has the patient had breast reconstructive surgery? ☐ (18)
0 - No reconstruction
1 - Yes, TRAM flap reconstruction (with or without implant)
2 - Yes, latissimus dorsi flap reconstruction (with or without implant)
3 - Yes, implant only
4 - Yes, reconstruction type not listed above

Record the first three letters of patient's last name and study ID on each of the remaining pages before giving the questionnaire to the patient.

First Three Letters of Patient's Last Name _________ **Patient Study ID**________________________________

INSTRUCTIONS TO PATIENT

Please complete the following questionnaire by circling the number that corresponds to your response to each question. If you have any questions about how to answer the items in this questionnaire, please ask a staff member for help. Please use a pencil (rather than a pen) so that you will be able to erase a circle if you decide to change your response.

All information collected in this questionnaire will be kept confidential and will be used only for research purposes. If you feel uncomfortable about answering any question(s), you may leave the item blank. Your answers will not affect your continued participation in the B-32 trial.

Please write the date in the boxes provided below.

Date this questionnaire is completed:

(For example, if you were completing the questionnaire on September 8, 2000, you would write 09 08 2000 in the boxes.)

Month	Day	Year	
☐☐	☐☐	☐☐☐☐	(19-26)

In the past 7 days, how difficult has it been for you to do the following activities? Even if you do not normally perform an activity listed below, or your doctor or nurse has advised you not to perform an activity listed below, please choose the answer that best applies to you. **We are not asking you to attempt these activities.**

	Not Difficult	**Somewhat Difficult**	**Very Difficult**	**I Could Not Do This**	
1. Push or pull large objects like a living room chair.	0	1	2	3	(27)
2. Lift items over 10 pounds, like a heavy bag of groceries with your ***RIGHT*** arm.	0	1	2	3	(28)
3. Lift items over 10 pounds, like a heavy bag of groceries with your ***LEFT*** arm.	0	1	2	3	(29)
4. Reach or extend your arms above shoulder level.	0	1	2	3	(30)

First Three Letters of Patient's Last Name _________ **Patient Study ID**________________________________

5. In the past 7 days, how often have you avoided using your ***RIGHT arm?***

Never Avoided	Seldom Avoided	Often Avoided	Always Avoided	
0	1	2	3	(31)

6. In the past 7 days, how often have you avoided using your ***LEFT arm?***

Never Avoided	Seldom Avoided	Often Avoided	Always Avoided	
0	1	2	3	(32)

In the past 7 days, how much have you been bothered by each of the following problems ***in your RIGHT underarm, arm, hand, fingers***?

	Not Bothered	A Little Bothered	Somewhat Bothered	Quite Bothered	Very Bothered	
7. Tenderness	0	1	2	3	4	(33)
8. Swelling	0	1	2	3	4	(34)
9. Discomfort or pain	0	1	2	3	4	(35)
10. Numbness or "pins & needles"	0	1	2	3	4	(36)
11. Increased skin sensitivity	0	1	2	3	4	(37)
12. Tightness, pulling, or stretching	0	1	2	3	4	(38)
13. Weakness	0	1	2	3	4	(39)

First Three Letters of Patient's Last Name _________ **Patient Study ID**________________________________

<u>In the past 7 days</u>, how much have you been bothered by each of the following problems ***in your RIGHT breast and/or right chest area***?

	Not Bothered	A Little Bothered	Somewhat Bothered	Quite Bothered	Very Bothered	
14. Tenderness	0	1	2	3	4	(40)
15. Swelling	0	1	2	3	4	(41)
16. Discomfort or pain	0	1	2	3	4	(42)
17. Numbness or "pins & needles"	0	1	2	3	4	(43)
18. Increased skin sensitivity	0	1	2	3	4	(44)
19. Tightness, pulling, or stretching	0	1	2	3	4	(45)

In the past 7 days, how much have you been bothered by each of the following problems ***in your LEFT underarm, arm, hand, and fingers***

	Not Bothered	A Little Bothered	Somewhat Bothered	Quite Bothered	Very Bothered	
20. Tenderness	0	1	2	3	4	(46)
21. Swelling	0	1	2	3	4	(47)
22. Discomfort or pain	0	1	2	3	4	(48)
23. Numbness or "pins & needles"	0	1	2	3	4	(49)
24. Increased skin sensitivity	0	1	2	3	4	(50)
25. Tightness, pulling, or stretching	0	1	2	3	4	(51)
26. Weakness	0	1	2	3	4	(52)

First Three Letters of Patient's Last Name _________ **Patient Study ID**________________________________

In the past 7 days, how much have you been bothered by each of the following problems ***in your LEFT breast and/or left chest area***?

	Not Bothered	A Little Bothered	Somewhat Bothered	Quite Bothered	Very Bothered	
27. Tenderness	0	1	2	3	4	(53)
28. Swelling	0	1	2	3	4	(54)
29. Discomfort or pain	0	1	2	3	4	(55)
30. Numbness or "pins & needles"	0	1	2	3	4	(56)
31. Increased skin sensitivity	0	1	2	3	4	(57)
32. Tightness, pulling, or stretching	0	1	2	3	4	(58)

33. In the past 7 days, to what extent were you limited in your normal ***social and/or recreational activities*** with family, friends, neighbors, or groups, due to problems with your underarms, arms, or hands?

Not Limited	A Little Limited	Somewhat Limited	Quite Limited	Very Limited	
0	1	2	3	4	(59)

34. In the past 7 days, to what extent were you limited in your ***work or other regular daily activities*** due to problems with your underarms, arms, or hands?

Not Limited	A Little Limited	Somewhat Limited	Quite Limited	Very Limited	
0	1	2	3	4	(60)

35. Please score your overall quality of life in the past 7 days on an 11-point scale where 0 indicates being in the worst possible health and 10 indicates being in perfect health.

0	1	2	3	4	5	6	7	8	9	10	(61-62)
worst possible health										**perfect health**	