Follow-Up Form
Breast (BRCA)

Instructions: *The Follow-up Form is to be completed 12 months after a case enters the Biospecimen Core Resource (BCR). All information provided on this form includes activity from the "Date of Last Contact" provided on the TCGA Enrollment Form to the most recent date of contact with the patient. This form should only be completed by the Tissue Source Site if updated information can be provided to TCGA. Please direct any questions to the Clinical Outreach team at the BCR.*

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

Tissue Source Site (TSS): _____TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By *(Interviewer Name on OpenClinica)*: _____Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ No	Please note that the time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box. *Provided time intervals must begin with the date of initial pathologic diagnosis (i.e., biopsy or resection).* *Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.*
2	Is this Patient Lost to Follow-up?	☐ Yes ☐ No	Indicate whether the patient is lost to follow-up, as defined by the ACoS Commission on Cancer. This only includes cases where updated follow-up information has not been collected within the past 15 months and all efforts to contact the patient have been exhausted (this includes reviewing the Social Security death index). If the patient is lost to follow-up, the remaining questions can be left unanswered. 61333 *If the patient is **deceased** and a TCGA follow-up form has not yet been completed, the answer to this question should be "no," and the remaining applicable questions should be completed.*

Follow-Up Information

#	Data Element	Entry Alternatives	Working Instructions
3	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy *for the tumor submitted for TCGA*. . 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
4	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy *for the tumor submitted for TCGA*. . 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
5	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550

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#	Data Element	Entry Alternatives	Working Instructions
6	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 2939553
7	Month of Last Contact	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient is living, provide the month of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020
8	Day of Last Contact	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient is living, provide the day of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897022
9	Year of Last Contact	_____	If the patient is living, provide the year of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897024
10	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of last contact. 3008273 *Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.*
11	Month of Death	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient is deceased, provide the month of death. 2897026
12	Day of Death	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient is deceased, provide the day of death. 2897028
13	Year of Death	_____	If the patient is deceased, provide the year of death. 2897030
14	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of death. 3165475 *Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.*

New Tumor Event Information *Complete this section if the patient had a new tumor event. If the patient did not have a new tumor event (or if the TSS does not know) indicate this in the question below, and the remainder of this section can be skipped.*

Note: The New Tumor Event section on OpenClinica can be completed multiple times, if the patient had multiple New Tumor Events.

#	Data Element	Entry Alternatives	Working Instructions
15	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after initial treatment. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
16	Type of New Tumor Event	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. A new primary tumor is a tumor with a different histology as the tumor submitted to TCGA. 3119721

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#	Data Element	Entry Alternatives	Working Instructions
17	Anatomic Site of New Tumor Event	☐ Lung ☐ Bone ☐ Liver ☐ Brain ☐ Other, specify	Indicate the site of this new tumor event. 3108271
18	Other Site of New Tumor Event	_____	If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event. 3128033
19	Month of New Tumor Event	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. 3104044
20	Day of New Tumor Event	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
21	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046
22	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. 3392464 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
23	Additional treatment for New Tumor Event: *Surgery*	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
24	Month of Additional Surgery for New Tumor Event	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612
25	Day of Additional Surgery for New Tumor Event	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	If the patient had surgery for the new tumor event, provide the day this surgery was performed. 3427613
26	Year of Additional Surgery for New Tumor Event	_____	If the patient had surgery for the new tumor event, provide the year this surgery was performed. 3427614
27	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of additional surgery for new tumor event (loco-regional). 3008335 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
28	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
29	Additional treatment for New Tumor Event: *Pharmaceutical Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

#	Data Element	Entry Alternatives	Working Instructions
New Tumor Event: Molecular Markers Used for Tumor Prognosis			
30	Estrogen Receptor (ER) Status by IHC for this patient	☐ Positive (1%-100%) ☐ Negative (0%) ☐ Indeterminate ☐ Performed but not available ☐ Not performed *(skip to next molecular marker)*	If IHC estrogen receptor testing was performed, provide the result of the test. If this test was not performed, selected "not performed," and continue to the progesterone receptor questions. 3131865
31	IHC ER Percent Positive for this patient	☐ <10% (1-9%) ☐ 50-59% ☐ 10-19% ☐ 60-69% ☐ 20-29% ☐ 70-79% ☐ 30-39% ☐ 80-89% ☐ 40-49% ☐ 90-100%	If IHC estrogen receptor testing was performed, provide the percent of estrogen receptor positive by IHC. 3131869
32	IHC Intensity: Scale Used to determine ER Positivity for this Patient	☐ 4 Point Scale ☐ 3 Point Scale	Using the pathology/laboratory report, indicate the intensity scale used for the estrogen receptor positivity score. 3203082
33	IHC Intensity: ER Positivity Score for this patient	☐ 0 ☐ +3 ☐ +1 ☐ +4 ☐ +2	Provide the positivity score using the IHC intensity scale, found on the pathology/laboratory report. 3131873
34	IHC Intensity: Other Method Used to Determine ER Positivity For this Patient	_____	If another scale was used to measure the estrogen receptor positivity, please describe the scale used. 3131877
35	Define Method of Calculation for ER Positivity if Other than IHC	_____	If a special method was used to calculate estrogen receptor status (e.g. dextran coated charcoal), describe the method used. 3131881
36	Progesterone Receptor (PR) Status by IHC for this patient	☐ Positive (1%-100%) ☐ Negative (0%) ☐ Indeterminate ☐ Performed but not available ☐ Not performed *(skip to next molecular marker)*	If IHC progesterone receptor testing was performed, provide the result of the test. If this test was not performed, select "not performed," and continue to the HER2/ERBB2 IHC questions. 3131884
37	IHC PR Percent Positive for this patient	☐ <10% (0-9%) ☐ 50-59% ☐ 10-19% ☐ 60-69% ☐ 20-29% ☐ 70-79% ☐ 30-39% ☐ 80-89% ☐ 40-49% ☐ 90-100%	If IHC progesterone receptor testing was performed, provide the percent of progesterone receptor positive nuclei by IHC. 3131891
38	IHC Intensity: Scale Used for PR Positivity	☐ 4 Point Scale ☐ 3 Point Scale	Using the pathology/laboratory report, indicate the intensity scale used for the progesterone receptor positivity score. 3203085
39	IHC Intensity: PR Positivity Score for this Patient	☐ 0 ☐ +3 ☐ +1 ☐ +4 ☐ +2	Provide the positivity score using the IHC intensity scale, found on the pathology/laboratory report. Only answer this question if PR status is considered positive; if the PR status was negative, continue to the HER2/ERBB2 IHC questions. 3131988
40	IHC Intensity: Other Method Used to Determine PR Positivity	_____	If another scale was used to measure the progesterone receptor positivity, please describe the scale used. 3131992
41	Define Method of Calculation for Positivity if Other Than IHC	_____	If a special method was used (other than IHC) to calculate progesterone receptor status (e.g. dextran coated charcoal), describe the method used. 3131993
42	HER2/ERBB2 Status by IHC for this Patient	☐ Positive ☐ Negative ☐ Equivocal ☐ Indeterminate ☐ Performed but not available ☐ Not performed*(skip to next molecular marker)*	If IHC HER2/ERBB2 testing was performed, provide the result of the test. If this test was not performed, select "not performed," and continue to the HER2/ERBB2 FISH questions. 3131997
43	IHC HER2/ERBB2 Percent Positive for this patient	☐ <10% ☐ 50-59% ☐ 10-19% ☐ 60-69% ☐ 20-29% ☐ 70-79% ☐ 30-39% ☐ 80-89%	If IHC HER2/ERBB2 testing was performed, provide the percent of HER2/ERBB2 positive by IHC. If HER2/ERBB2 was negative, continue to the HER2/ERBB2 FISH questions. 3132322

#	Data Element	Entry Alternatives	Working Instructions
		☐ 40-49% ☐ 90-100%	
44	IHC Intensity: HER2/ERBB2 Positivity Score for this Patient	☐ 0 ☐ +2 ☐ +1 ☐ +3	Provide the positivity score using the IHC intensity scale, found on the pathology/laboratory report. 3132444
45	Other Scale Used to Measure HER2/ERBB2 Positivity	_____	If an additional scale was used to measure HER2/ERBB2 positivity, please describe the scale used. 3132448
46	Define method of calculation for HER2/ERBB2 Positivity	_____	If a special method was used to calculate HER2/ERBB2 status, describe the method used. 3132452
47	HER2/ERBB2 Status by FISH for this Patient	☐ Positive ☐ Negative ☐ Equivocal ☐ Indeterminate ☐ Performed but not available ☐ Not performed *(skip to next molecular marker)*	If HER2/ERBB2 FISH testing was performed, provide the result of the test. If this test was not performed, select "not performed." 3132455
48	Number of HER2 FISH Signals for this Patient	_____	If HER2 copy number testing was performed by FISH, provide the average number of HER2 FISH signals for this patient. If this test was not performed, leave this question blank and move to the next question. 3133734
49	Number of Centromere 17 Signals for this Patient	_____	If Centromere 17 copy number testing was performed by FISH, provide the average number of Centromere 17 signals for this patient. If this test was not performed, leave this question blank and move to the next question. 3132887
50	Number of Cells Counted for HER2 & Centromere 17 by FISH for this Patient	_____	Indicate the total number of cells counted by FISH for HER2 & Centromere 17 copy numbers. If these tests were not performed, leave this question blank and move to the next question. 3132899
51	HER2/Centromere 17 Ratio for this Patient	_____	If HER2 copy number and Centromere 17 copy number testing was performed by FISH, provide the ratio of the outcomes of these tests. *(For example, if both the HER2 copy number and the Centromere 17 copy number equal 2, the ratio would be 2÷2 or 1.0.)* 3132903
52	Other Scale Used to Measure HER2 & Centromere 17 Positivity *(Please Include Score)*	_____	If an additional scale was used to measure HER2 & Centromere 17 positivity, please describe the scale used. 3132907
53	Define Method of Calculation for HER2/ERBB2 Positivity if other than IHC or FISH	_____	If a special method was used to calculate HER2 & Centromere 17 positivity, describe the method used. 3132910

_____ _____ ___ ___/ ___ ___/ ___ ___ ___ ___

Principal Investigator or Designee Signature | Print Name | Date