Enrollment Form
Breast (BRCA)

Instructions: *The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity from the date of initial diagnosis to the most recent date of contact with the patient ("Date of Initial Pathologic Diagnosis" and "Date of Last Contact" on this form).*

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact 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 cannot answer the question because the answer is not known at the TSS. 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 be selected by the TSS if it is known that the information being requested cannot be obtained. If for example, a test was not performed the results of that test cannot be provided because it was "Not Evaluated."

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

Completed By *(Interviewer Name in 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	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. Provided time intervals must begin with the date of initial pathologic diagnosis (e.g. biopsy). 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 a prospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively. 3088492
3	Is this a retrospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively. 3088528

Patient Information

#	Data Element	Entry Alternatives	Working Instructions
4	Month of Birth	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	Provide the month the patient was born. 2896950
5	Day of Birth	☐ 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	Provide the day the patient was born. 2896952
6	Year of Birth	_____	Provide the year the patient was born. 2896954

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#	Data Element	Entry Alternatives	Working Instructions
7	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth. 3008233 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.
8	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
9	Menopause Status *(at time of diagnosis)*	☐ Premenopausal ☐ Perimenopausal ☐ Postmenopausal ☐ Indeterminate or Unknown ☐ Not Evaluated	Using the patient's medical records, indicate menopause status at the time the patient was diagnosed with the malignancy submitted for TCGA. 2957270 Premenopausal: *<6 months since LMP AND no prior bilateral oophorectomy AND not on estrogen replacement* Perimenopausal: *6-12 months since last menstrual period* Postmenopausal: *Prior bilateral ovariectomy OR > 12 months since LMP with no prior hysterectomy* Indeterminate: *Unknown*
10	Race	☐ American Indian or Alaska Native *A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.* ☐ Asian *A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.* ☐ White *A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.* ☐ Black or African American *A person having origins in any of any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."* ☐ Native Hawaiian or other Pacific Islander: *A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.* ☐ Not Evaluated *Not provided or available.* ☐ Unknown *Could not be determined or unsure.*	Provide the patient's race using the defined categories. 2192199
11	Ethnicity	☐ Not Hispanic or Latino: *A person not meeting the definition of Hispanic or Latino.* ☐ Hispanic or Latino: *A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.* ☐ Not Evaluated *Not provided or available.* ☐ Unknown *Could not be determined or unsure.*	Provide the patient's ethnicity using the defined categories. 2192217
12	History of Other Malignancy	☐ Yes ☐ No	Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time. 3382736 If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.

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13	Neo-adjuvant (pre-operative) therapy	☐ Yes ☐ No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737 Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted sample) given prior to the collection of the sample submitted for TCGA is exclusionary.
14	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
15	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
16	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 Do not answer if patient is deceased.
17	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 Do not answer if patient is deceased.
18	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 Do not answer if patient is deceased.
19	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.
20	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
21	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
22	Year of Death	_____	If the patient is deceased, provide the year of death. 2897030
23	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.

#	Data Element	Entry Alternatives	Working Instructions
24	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.
25	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.

Pathologic/Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
26	Primary Site of Disease	☐ Breast	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776 The tumor submitted for TCGA must be located in the endometrium; indicate other involvement, as initially diagnosed.
27	Anatomic Organ Sub-Division	☐ Right Breast ☐ UIQ ☐ UOQ ☐ LIQ ☐ LOQ ☐ Left Breast ☐ UIQ ☐ UOQ ☐ LIQ ☐ LOQ	Using the patient's pathology/laboratory report, select the anatomic organ sub-division of the tumor used for TCGA. Include all areas of tumor invasion. 2008006
28	Histological Subtype	☐ Infiltrating Ductal Carcinoma ☐ Infiltrating Lobular Carcinoma ☐ Infiltrating Carcinoma, NOS ☐ Mucinous Carcinoma ☐ Medullary Carcinoma ☐ Metaplastic Carcinoma ☐ Mixed Histology, specify ☐ Other, specify	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. ***Mixed Histology***: The specimen is mixed with ductal and lobular carcinomas only. ***Other***: Any other histology mixed with ductal and/or lobular OR rare/special histological types. 2549638
29	Other Histological Subtype or Mixed Diagnosis	_____	If the histological subtype on the pathology/laboratory report does not fall under the provided histological types, describe the histology and/or subtype here. 3124492
30	Month of Initial Pathologic Diagnosis	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	Provide the month the patient was initially diagnosed with the malignancy submitted for TCGA. 2896956
31	Day of Initial Pathologic Diagnosis	☐ 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	Provide the day the patient was initially diagnosed with the malignancy submitted for TCGA. 2896958
32	Year of Initial Pathologic Diagnosis	_____	Provide the year the patient was initially diagnosed with the malignancy submitted for TCGA. 2896960
33	Age at Initial Diagnosis	_____	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657 Only complete this question if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.

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#	Data Element	Entry Alternatives	Working Instructions
34	Method of Initial Pathologic Diagnosis	☐ Cytology ☐ Fine needle aspiration biopsy ☐ Core needle biopsy ☐ Incision biopsy ☐ Excisional biopsy ☐ Tumor resection ☐ Other method, please specify	Provide the procedure used to initially diagnose the patient. 2757941
35	Other Method of Initial Pathologic Diagnosis	_____	If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used. 2757948
36	First Surgical Procedure	☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Unknown ☐ Other, specify	Provide the first procedure used after the initial diagnosis. 2739580
37	Other First Surgical Procedure	_____	If the first procedure used after the initial diagnose was not included in the list provided, please describe the method used. 3020338
38	Margin Status after First Surgical Procedure	☐ Positive (+) ☐ Negative (-) ☐ Close ☐ Unknown	Provide the margin status after the patient's first surgical procedure. 3114007
39	If margins were positive after first surgical resection, what was the surgical procedure performed to achieve negative margins?	☐ Surgery not performed ☐ Lumpectomy ☐ Mastectomy ☐ Modified radical mastectomy ☐ Unknown ☐ Other, specify	If margins were positive after the first surgical resection, provide the additional surgery performed to ensure negative margins. 1218
40	Other Surgical Method Performed to Achieve Negative Margins	_____	If the additional procedure used after the first surgery resulted in positive margins was not included in the list provided, please describe the method used. 3124493
41	Margin Status after second surgical resection	☐ Positive (+) ☐ Negative (-) ☐ Close ☐ Unknown	Provide the margin status after the additional procedure used after the first surgery resulted in positive margins. 2241252
42	Axillary Staging Method	☐ No axillary staging ☐ Sentinel lymph node biopsy alone ☐ Sentinel lymph node biopsy plus axillary dissection ☐ Axillary lymph node dissection alone ☐ Unknown ☐ Other, specify	Using the pathology/laboratory report, provide the axillary staging method used to detect nodal involvement. 2516112
43	Other method of Axillary Staging	_____	If the axillary staging method used was not included in the list provided, please describe the method used. 3124496
44	Was IHC Staining used to Detect Micro metastasis?	☐ Yes ☐ No ☐ Unknown	Indicate whether immunohistochemistry (IHC) staining was performed to detect micro metastasis. 3086152
Lymph Node Status			
45	Were Lymph Nodes Examined at the Time of Primary Resection?	☐ Yes ☐ No ☐ Unknown	Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396
46	Number of Lymph Nodes Examined	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3

#	Data Element	Entry Alternatives	Working Instructions
47	Number of Lymph Nodes Positive by H&E light microscopy	_____	Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy. 3086388
48	Number of Lymph Nodes Positive by IHC Keratin Staining only	_____	Provide the number of lymph nodes positive through keratin immunohistochemistry (IHC) staining. 3086383
AJCC Staging			
49	AJCC Cancer Staging Edition	☐ 1st Edition *(1978-1983)* ☐ 2nd Edition *(1984-1988)* ☐ 3rd Edition *(1989-1992)* ☐ 4th Edition *(1993-1997)* ☐ 5th Edition *(1998-2002)* ☐ 6th Edition *(2003-2009)* ☐ 7th Edition *(2010-present)*	Based on the date the patient was staged select the AJCC edition used to stage the patient. 2722309
50	Pathologic T Stage	☐ TX ☐ T0 ☐ Tis ☐ Tis (DCIS) ☐ Tis (LCIS) ☐ Tis (Paget's) ☐ T1mic ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3045435
51	Pathologic N Stage	☐ NX ☐ N0 ☐ N0 (i-) ☐ N0 (i+) ☐ N0 (mol-) ☐ N0 (mol+) ☐ N1 ☐ N1mi ☐ N1a ☐ N1b ☐ N1bi ☐ N1bii ☐ N1biii ☐ N1biv ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ N3 ☐ N3a ☐ N3b ☐ N3c	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3203106
52	Pathologic M Stage	☐ MX ☐ M0 ☐ cM0 (i+) ☐ M1	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC). 3045439
53	Stage	☐ Stage X ☐ Stage Tis ☐ Stage 0 ☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	Using the patient's pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3203222
54	Site of First Non-Nodal Metastatic Tumor *If metastasis were found at multiple sites simultaneously, check all that apply*	☐ Lung ☐ Bone ☐ Liver ☐ Brain ☐ Unknown ☐ Other, specify	If the patient had a non-nodal metastasis associated with the diagnosis of the tumor submitted for TCGA, provide the site of the first non-nodal metastasis. Only select more than one site if there were synchronous metastasis where the first non-nodal met was found at multiple sites. 3124499
55	Other Site of First Non-Nodal Metastatic Tumor	_____	If the site of the first non-nodal metastasis was not included in the list provided, please provide the site. 3124503

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#	Data Element	Entry Alternatives	Working Instructions
Primary Tumor Molecular Markers Used for Tumor Prognosis			
56	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. 2957359
57	IHC ER Percent Positive	☐ <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. 3128341
58	IHC Intensity Scale Used for ER Positivity	☐ 4 Point Scale ☐ 3 Point Scale	Using the pathology/laboratory report, indicate the intensity scale used for the estrogen receptor positivity score. 3203081
59	IHC Intensity Used to Define ER Positivity	☐ +1 (3 Point Scale) ☐ +2 (3 Point Scale) ☐ +3 (3 Point Scale) ☐ +1 (4 Point Scale) ☐ +2 (4 Point Scale) ☐ +3 (4 Point Scale) ☐ +4 (4 Point Scale)	Provide the positivity score using the IHC intensity scale, found on the pathology/laboratory report. 2230166
60	Other Scale Used to Measure ER Positivity	_____	If another scale was used to measure the estrogen receptor positivity, please describe the scale used. 3086851
61	Define Method of Calculation for ER Positivity	_____	If a special method was used to calculate estrogen receptor status (e.g. dextran coated charcoal), describe the method used. 69
62	Progesterone Receptor (PR) Status by IHC	☐ 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. 2957357
63	IHC PR Percent Positive	☐ <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. 3128342
64	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. 3203083
65	IHC Intensity: PR Positivity Score	☐ +1 (3 Point Scale) ☐ +2 (3 Point Scale) ☐ +3 (3 Point Scale) ☐ +1 (4 Point Scale) ☐ +2 (4 Point Scale) ☐ +3 (4 Point Scale) ☐ +4 (4 Point Scale)	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. 3133874
66	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. 3086857
67	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. 785

#	Data Element	Entry Alternatives	Working Instructions
68	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. 2957563
69	IHC HER2/ERBB2 Percent Positive for this patient	☐ <10% ☐ 10-19% ☐ 20-29% ☐ 30-39% ☐ 40-49% ☐ 50-59% ☐ 60-69% ☐ 70-79% ☐ 80-89% ☐ 90-100%	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. 3086980
70	IHC Intensity: HER2/ERBB2 Positivity Score for this Patient	☐ +1 (3 Point Scale) ☐ +2 (3 Point Scale) ☐ +3 (3 Point Scale) ☐ +1 (4 Point Scale) ☐ +2 (4 Point Scale) ☐ +3 (4 Point Scale) ☐ +4 (4 Point Scale)	Provide the positivity score using the IHC intensity scale, found on the pathology/laboratory report. 2178402
71	Other Scale Used to Measure HER2/ERBB2 Positivity	_____	If an additional scale was used to measure HER2/ERBB2 positivity, please describe the scale used. 3087479
72	Define method of calculation for HER2/ERBB2 Positivity	_____	If a special method was used to calculate HER2/ERBB2 status, describe the method used. 3087487
73	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." 2854089
74	HER2 Copy Number	_____	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. 3133738
75	Centromere 17 Copy Number	_____	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. 3104295
76	Number of Cells Counted for HER2 & Centromere 17 Copy Numbers	_____	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. 3087902
77	HER2/Centromere 17 Ratio	_____	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.)* 2497552
78	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. 3087923
79	Define method of calculation for HER2 / ERBB2 FISH Positivity	_____	If a special method was used to calculate HER2 & Centromere 17 positivity, describe the method used. 3087929

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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.*

#	Data Element	Entry Alternatives	Working Instructions
80	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.
81	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
82	Anatomic Site of New Tumor Event	☐ Lung ☐ Brain ☐ Bone ☐ Unknown ☐ Liver ☐ Other, specify	Indicate the site of this new tumor event. 3108271
83	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
84	Month of New Tumor Event	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. 3104044
85	Day of New Tumor Event	☐ 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 had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
86	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046
87	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.
88	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
89	Month of Additional Surgery for New Tumor Event	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612
90	Day of Additional Surgery for New Tumor Event	☐ 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 had surgery for the new tumor event, provide the day this surgery was performed. 3427613
91	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

#	Data Element	Entry Alternatives	Working Instructions
92	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.
93	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
94	Additional treatment for New Tumor Event: *Pharmaceutical Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616
New Tumor Event: Molecular Markers Used for Tumor Prognosis			
95	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
96	IHC ER Percent Positive for this patient	☐ <10% (1-9%) ☐ 10-19% ☐ 20-29% ☐ 30-39% ☐ 40-49% ☐ 50-59% ☐ 60-69% ☐ 70-79% ☐ 80-89% ☐ 90-100%	If IHC estrogen receptor testing was performed, provide the percent of estrogen receptor positive by IHC. 3131869
97	IHC Intensity: Scale Used to determine ER Positivity	☐ 4 Point Scale ☐ 3 Point Scale	Using the pathology/laboratory report, indicate the intensity scale used for the estrogen receptor positivity score. 3203082
98	IHC Intensity Used to Define ER Positivity	☐ +1 (3 Point Scale) ☐ +2 (3 Point Scale) ☐ +3 (3 Point Scale) ☐ +1 (4 Point Scale) ☐ +2 (4 Point Scale) ☐ +3 (4 Point Scale) ☐ +4 (4 Point Scale)	Provide the positivity score using the IHC intensity scale, found on the pathology/laboratory report. 3131873
99	Other Scale Used to Measure ER Positivity	_____	If another scale was used to measure the estrogen receptor positivity, please describe the scale used. 3131877
100	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
101	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
102	IHC PR Percent Positive for this patient	☐ <10% (0-9%) ☐ 10-19% ☐ 20-29% ☐ 30-39% ☐ 40-49% ☐ 50-59% ☐ 60-69% ☐ 70-79% ☐ 80-89% ☐ 90-100%	If IHC progesterone receptor testing was performed, provide the percent of progesterone receptor positive nuclei by IHC. 3131891
103	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

#	Data Element	Entry Alternatives	Working Instructions
104	IHC Intensity: PR Positivity Score for this Patient	☐ +1 (3 Point Scale) ☐ +2 (3 Point Scale) ☐ +3 (3 Point Scale) ☐ +1 (4 Point Scale) ☐ +2 (4 Point Scale) ☐ +3 (4 Point Scale) ☐ +4 (4 Point Scale)	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
105	Other Scale Used to Measure PR Positivity	_____	If another scale was used to measure the progesterone receptor positivity, please describe the scale used. 3131992
106	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
107	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
108	IHC HER2/ERBB2 Percent Positive for this patient	☐ <10% ☐ 10-19% ☐ 20-29% ☐ 30-39% ☐ 40-49% ☐ 50-59% ☐ 60-69% ☐ 70-79% ☐ 80-89% ☐ 90-100%	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
109	IHC Intensity: HER2/ERBB2 Positivity Score for this Patient	☐ +1 (3 Point Scale) ☐ +2 (3 Point Scale) ☐ +3 (3 Point Scale) ☐ +1 (4 Point Scale) ☐ +2 (4 Point Scale) ☐ +3 (4 Point Scale) ☐ +4 (4 Point Scale)	Provide the positivity score using the IHC intensity scale, found on the pathology/laboratory report. 3132444
110	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
111	Define method of calculation for HER2/ERBB2 Positivity	_____	If a special method was used to calculate HER2/ERBB2 status, describe the method used. 3132452
112	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
113	HER2 Copy Number	_____	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
114	Centromere 17 Copy Number	_____	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
115	Number of Cells Counted for HER2 & Centromere 17 Copy Numbers	_____	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

#	Data Element	Entry Alternatives	Working Instructions
116	HER2/Centromere 17 Ratio	_____	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
117	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
118	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