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.

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<table>
<thead>
<tr>
<th>#</th>
<th>Data Element</th>
<th>Entry Alternatives</th>
<th>Working Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Is this Patient Lost to Follow-up?</td>
<td>□ Yes □ No</td>
<td>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. <strong>61333</strong> 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.</td>
</tr>
</tbody>
</table>

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Follow-Up Information

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>2</td>
<td>Adjuvant (Post-Operative) Radiation Therapy</td>
<td>□ Yes □ No □ Unknown</td>
<td>Indicate whether the patient had adjuvant/post-operative radiation therapy. <strong>2005312</strong> If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.</td>
</tr>
<tr>
<td>3</td>
<td>Adjuvant (Post-Operative) Pharmaceutical Therapy</td>
<td>□ Yes □ No □ Unknown</td>
<td>Indicate whether the patient had adjuvant/post-operative pharmaceutical therapy. <strong>3397567</strong> If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</td>
</tr>
<tr>
<td>4</td>
<td>Has the patient ever taken menopausal hormone therapy?</td>
<td>□ Current User □ Former User □ Never Used □ Unknown</td>
<td>Indicate whether the patient, at any time, used menopausal hormone therapy. <strong>3012813</strong></td>
</tr>
<tr>
<td>5</td>
<td>Has the patient ever taken oral contraceptives?</td>
<td>□ Current User □ Former User □ Never Used □ Unknown</td>
<td>Indicate whether the patient, at any time, used oral contraceptives. <strong>3104217</strong></td>
</tr>
<tr>
<td>6</td>
<td>Has the patient ever taken Tamoxifen?</td>
<td>□ Current User □ Former User □ Never Used □ Unknown</td>
<td>Indicate whether the patient, at any time, used Tamoxifen. <strong>3104234</strong></td>
</tr>
<tr>
<td>7</td>
<td>Hypertension</td>
<td>□ Yes □ No □ Unknown</td>
<td>Indicate whether the patient has a history of hypertension. <strong>2183378</strong></td>
</tr>
</tbody>
</table>
### Data Element: Has the patient ever been diagnosed with diabetes by a physician?
- Yes
- No
- Unknown

**Working Instructions:**
Indicate whether the patient has, at any time, been diagnosed with diabetes by a physician. This includes borderline and gestational diabetes.  

**Value:**
2716085

### Data Element: Number of full term pregnancies
- 0
- 1
- 2
- 3
- 4+
- Unknown

**Working Instructions:**
Provide the number of full term pregnancies the patient has had.

**Value:**
3012512

### Data Element: Has the patient had colorectal cancer?
- Yes
- No
- Unknown

**Working Instructions:**
Indicate whether the patient has a history of colorectal cancer.

**Value:**
2684753

### Data Element: Tumor Status (at time of last contact or death)
- Tumor free
- With tumor
- Unknown

**Working Instructions:**
Indicate whether the patient was tumor/disease free at the date of last contact or death.

**Value:**
2759550

### Data Element: Vital Status (at date of last contact)
- Living
- Deceased

**Working Instructions:**
Indicate whether the patient was living or deceased at the date of last contact.

**Value:**
8

### Data Element: Date of Last Contact

**Working Instructions:**
If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver).

**Values:** 2897020 (month), 2897022 (day), 2897024 (year)

### Data Element: Date of Death

**Working Instructions:**
If the patient is deceased, provide the date of death.

**Values:** 2897026 (month), 2897028 (day), 2897030 (year)

### Data Element: Measure of success of outcome at the completion of initial first course treatment
- Progressive Disease
- Stable Disease
- Partial Response
- Complete Response
- Not Applicable (Treatment Ongoing)
- Unknown

**Working Instructions:**
Provide the patient's response to their initial first course treatment.

**Value:**
2786727

### Data Element: New Tumor Event After Initial Treatment?
- Yes
- No
- Unknown

**Working Instructions:**
Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after initial treatment.

**Value:**
3121376

### Data Element: Type of New Tumor Event
- Locoregional Recurrence
- Distant Metastasis
- Progression of Disease

**Working Instructions:**
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.

**Value:**
3119721

### Data Element: Site of New Tumor Event
- Abdomen
- Bone
- Brain
- Liver
- Lung
- Lymph Node
- Pelvis
- Unknown
- Other, specify

**Working Instructions:**
Indicate the site of this new tumor event.

**Value:**
3108271

### Data Element: Other Site of New Tumor Event

**Working Instructions:**
If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event.

**Value:**
3128033

---

**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.*
<table>
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<tr>
<td>20</td>
<td>Date of New Tumor Event</td>
<td>_____ _____/ _____ _____/ _____ _____ (month)* (day) (year)*</td>
<td>If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (month), 3104042 (day), 3104046 (year)</td>
</tr>
<tr>
<td>21</td>
<td>Additional treatment for New Tumor Event: Surgery</td>
<td>Yes, No, Unknown</td>
<td>Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611</td>
</tr>
<tr>
<td>22</td>
<td>Month of Additional Surgery for New Tumor Event</td>
<td>_____ _____/ _____ _____/ _____ _____ (month)* (day) (year)*</td>
<td>If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612 (month), 3427613 (day), 3427614 (year)</td>
</tr>
<tr>
<td>23</td>
<td>Procedure Type for New Tumor Event</td>
<td>Excisional Biopsy, Incisional Biopsy, Surgical Resection, Unknown, Other Method, Specify Below</td>
<td>If the patient had surgery for the new tumor event, provide the type of procedure performed for this tumor. 3125097</td>
</tr>
<tr>
<td>24</td>
<td>Other Procedure Type for New Tumor Event</td>
<td></td>
<td>If the procedure for the new tumor event was not included in the list provided, indicate the type of procedure performed. 3125102</td>
</tr>
<tr>
<td>25</td>
<td>Residual Tumor After surgery for New Tumor Event</td>
<td>RX: The presence of residual tumor or margin status cannot be assessed. R0: No residual tumor and negative microscopic margins in resected specimen. R1: Microscopic residual tumor. No gross residual disease but positive microscopic margins. R2: Macroscopic residual tumor. Grossly visible residual disease.</td>
<td>Using the patient's pathology/laboratory report, select the residual tumor status after the surgical resection for the new tumor event. 3104061</td>
</tr>
<tr>
<td>26</td>
<td>Additional treatment for New Tumor Event: Radiation Therapy</td>
<td>Yes, No, Unknown</td>
<td>Indicate whether the patient received radiation treatment for this new tumor event. 3427615</td>
</tr>
<tr>
<td>27</td>
<td>Additional treatment for New Tumor Event: Pharmaceutical Therapy</td>
<td>Yes, No, Unknown</td>
<td>Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616</td>
</tr>
</tbody>
</table>

Principal Investigator or Designee Signature  ____________________________     Print Name  ____________________________     Date  __/__/____