Follow-Up Form Thyroid (THCA)

V4.01 052512

Completed Date: _____

<u>Instructions</u>: 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.

Completed By (Interviewer Name on OpenClinica): ______

General Information # **Data Element Entry Alternatives** Working Instructions Please note that the time intervals must be recorded in place Has this TSS received of dates where designated throughout this form if you have permission from the selected "yes" in the box. NCI to provide time □ Yes Provided time intervals must begin with the date of initial 1 intervals as a substitute 🗖 No pathologic diagnosis (i.e., biopsy or resection). for requested dates on Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested this form? dates on this form. 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 Is this Patient Lost to Yes Security death index). If the patient is lost to follow-up, the 2 remaining questions can be left unanswered. 🗖 No Follow-up? 61333 If the patient is **deceased** and a TCGA follow-up form has not vet 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. <u>2005312</u> 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. <u>3397567</u> 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
6	Vital Status (at date of last contact)	□ Living □ Deceased	Indicate whether the patient was living or deceased at the date of last contact. $\underline{5}$

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		T i i i			
#	Data Element	Entry Alternativ	es		Working Instructions
7	Month of Last Contact	□ 01 □ 04 □ 02 □ 05 □ 03 □ 06	□ 07 □ 08 □ 09	□ 10 □ 11 □ 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). <u>2897020</u> Do not answer if patient is deceased.
8	Day of Last Contact	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	14 20 15 21 16 22 17 23 18 24 19 25	□ 26 □ 27 □ 28 □ 29 □ 30 □ 31	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). <u>2897022</u> Do not answer if patient is deceased.
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). <u>2897024</u> Do not answer if patient is deceased.
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. <u>3008273</u> 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 □ 02 □ 05 □ 03 □ 06	□ 07 □ 08 □ 09	□ 10 □ 11 □ 12	If the patient is deceased, provide the month of death. 2897026
12	Day of Death	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	14 20 15 21 16 22 17 23 18 24 19 25	□ 26 □ 27 □ 28 □ 29 □ 30 □ 31	If the patient is deceased, provide the day of death. <u>2897028</u>
13	Year of Death			-	If the patient is deceased, provide the year of death. <u>2897030</u>
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. <u>3165475</u> 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.

Treatment Information

#	Data Element	Entry Alternatives	Working Instructions	
Adj	Adjuvant I-131 Therapy and Radiation Therapy (XRT) For Primary Tumor			
15	I-131 Treatment: Method of preparation	 rhTSH Thyroxine withdrawal Patient did not receive I-131treatment Unknown 	If the patient received I-131 therapy for the primary tumor, indicate the method used. <u>3232952</u> NOTE: If the patient did NOT receive I-131 therapy for the primary tumor, related questions can be skipped.	
16	I-131 Treatment: Dose of First Treatment		If the patient received I-131 therapy for the primary tumor, provide the dose of the first treatment. <u>3232898</u>	
17	I-131 Treatment: Subsequent Treatments		If the patient received I-131 therapy for the primary tumor, detail subsequent treatments. 3232904	
18	I-131 Treatment: Total Cumulative Dose		If the patient received I-131 therapy for the primary tumor, provide the total cumulative dose. <u>3232906</u>	

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#	Data Element	Entry Alternatives	Working Instructions		
19	Radiation Therapy (XRT): Method of preparation	 Hyperfractionated IMRT Patient did not receive external radiation therapy Unknown 	If the patient received radiation therapy for the primary tumor, indicate the method of preparation. 3232960		
20	Radiation Therapy (XRT): Dose Administered		If the patient received radiation therapy for the primary tumor, provide the dose administered. <u>3232933</u>		
21	Radiation Therapy (XRT): Radiation Sensitizers Administered	□ Yes □ No □ Unknown	If the patient received radiation therapy for the primary tumor, indicate whether or not radiation sensitizers were administered. <u>3232932</u>		
Clinical Status after Surgery					
22	Clinical Status Within Three (3) Months of Surgery	 No Imaging Evidence of Disease Persistent Locoregional Disease Persistent Distant Metastases Not Evaluated Unknown 	Indicate the patient's clinical status within three months of the surgery related to thyroid carcinoma submitted for TCGA. 3186684		

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
23	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. <u>3121376</u> If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
<u>24</u>	Type of New Tumor Event	 Locoregional Recurrence Distant Metastasis New Primary Tumor Biochemical Evidence of Disease 	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
<u>25</u>	Site of New Tumor Event	□ Lung□ Lymph Node(s)□ Bone□ Unknown□ Soft Tissue□ Other, specify	Indicate the site of this new tumor event. <u>3108271</u>
<u>26</u>	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
<u>27</u>	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
<u>28</u>	Day of New Tumor Event	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
<u>29</u>	Year of New Tumor Event		If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046
<u>30</u>	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. <u>3392464</u> 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.

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#	Data Element	Entry Alternatives	Working Instructions
<u>31</u>	New Tumor Event Diagnosis Confirmed By	□ Imaging □ Pathology □ Unknown	If the patient had a new tumor event, provide the method used to confirm this diagnosis. <u>3186701</u>
<u>32</u>	Evidence of Histologic Progression	☐ Yes ☐ No ☐ Unknown	Indicate whether the new tumor event had evidence of histologic progression. <u>3181376</u>
<u>33</u>	Type of Histologic Progression	 Poorly Differentiated Anaplastic Unknown Other, specify 	If the new tumor event had evidence of histologic progression, indicate the type of evidence. <u>3181384</u>
<u>34</u>	Other Type of Histologic Progression		If the histologic progression for the new tumor event is not included in the list provided, describe the type of progression. <u>3181387</u>
<u>35</u>	If lymph nodes are positive, specify site(s).	 Central (levels 6-7) Lateral (levels 2-5) Unknown Other, specify 	If the patient had positive lymph nodes, provide the site of the positive nodes. <u>3186207</u>
<u>36</u>	Other Site of Positive Lymph Nodes		If the patient had positive lymph nodes and the site is not included in the provided list, please indicate the location. 3185693
<u>37</u>	Additional Therapy Required for New Tumor Event <i>Check all that apply</i>	 Surgery RAI Therapy EBRT Pharmaceutical Therapy Unknown 	Indicate they type of additional therapy required for the new tumor event. 3185186
<u>38</u>	Additional treatment for New Tumor Event: <i>Surgery</i>	□ Yes □ No □ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. <u>3427611</u>
<u>39</u>	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. <u>3427612</u>
<u>40</u>	Day of Additional Surgery for New Tumor Event	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	If the patient had surgery for the new tumor event, provide the day this surgery was performed. <u>3427613</u>
<u>41</u>	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
<u>42</u>	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). <u>3008335</u> 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.

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#	Data Element	Entry Alternatives	Working Instructions
<u>43</u>	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	☐ Yes □ No □ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
<u>44</u>	Additional treatment for New Tumor Event: Pharmaceutical Therapy	☐ Yes □ No □ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. <u>3427616</u>
Adj	uvant I-131 Therapy and	Radiation Therapy (XRT) For New Tumor Ever	nt
<u>45</u>	I-131 Treatment: Method of preparation	 rhTSH Thyroxine withdrawal Patient did not receive I-131treatment Unknown 	If the patient received I-131 therapy for the new tumor event, indicate the method used. <u>3232952</u> NOTE: If the patient did NOT receive I-131 therapy for the new tumor event, related questions can be skipped.
<u>46</u>	I-131 Treatment: Dose of First Treatment		If the patient received I-131 therapy for the new tumor event, provide the dose of the first treatment. <u>3232898</u>
<u>47</u>	I-131 Treatment: Subsequent Treatments		If the patient received I-131 therapy for the new tumor event, detail subsequent treatments. <u>3232904</u>
<u>48</u>	I-131 Treatment: Total Cumulative Dose		If the patient received I-131 therapy for the new tumor event, provide the total cumulative dose. <u>3232906</u>
<u>49</u>	Radiation Therapy (XRT): Method of preparation	 Hyperfractionated IMRT Patient did not receive external radiation therapy Unknown 	If the patient received radiation therapy for the new tumor event, indicate the method of preparation. 3232960
<u>50</u>	Radiation Therapy (XRT): Dose Administered		If the patient received radiation therapy for the new tumor event, provide the dose administered. <u>3232933</u>
<u>51</u>	Radiation Therapy (XRT): Radiation Sensitizers Administered	□ Yes □ No □ Unknown	If the patient received radiation therapy for the new tumor event, indicate whether or not radiation sensitizers were administered. <u>3232932</u>

Principal Investigator or Designee Signature

Print Name

_/ _ Date