**About this form:**  The Texas Cancer Registry (TCR) reviews requests for cancer data before applications can be submitted to the Department of State Health Services (DSHS) Institutional Review Board (IRB). Please complete and return this form to CancerData@dshs.texas.gov as a Word document. The final TCR-approved version will be part of your IRB application packet.

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Request (select one)** | [ ]  New Application[ ]  Amendment | **Today’s Date** | Click to enter date. |
| **Submission Title** | Click to enter. |
| **DSHS IRB Number** (amendments only) | Click to enter. |

|  |
| --- |
| **Principal Investigator (PI)** |
| *Last Name* | Click to enter. | *First Name* | Click to enter. | *Degrees* | Click to enter. |
| *Title* | Click to enter. |
| *Institution* | Click to enter. |
| *Mailing Address* | Click to enter. |
| *Phone Number* | Click to enter. | *Email* | Click to enter. |
| **Primary Study Contact** (if different from PI) |
| *Last Name* | Click to enter. | *First Name* | Click to enter. | *Degrees* | Click to enter. |
| *Title* | Click to enter. |
| *Institution* | Click to enter. |
| *Mailing Address* | Click to enter. |
| *Phone Number* | Click to enter. | *Email* | Click to enter. |
| **Summary Description of the Research Project** |
| Provide a brief description of the research project. Keep this section to one page (single-spaced) with no more than five references. This section should focus on the aspect of your research that involves TCR data, including how TCR data will be used and why it is needed to achieve your study aims. To provide additional context and information about your study, you can attach a copy of your study protocol for the initial TCR program review. |
| **Primary Focus**  |
| Click to enter text. |
| **Objectives** |
| Click to enter text. |
| **Study Design** (e.g., cross-sectional, retrospective cohort, prospective cohort) |
| Click to enter text. |
| **Methods** (relevant to TCR data, such as data linkage or patient contact study) |
| Click to enter text. |
| **Data Analyses** (state specifically how TCR data will be used in the analyses) |
| Click to enter text. |
| **Data Products Planned** (e.g., internal or external presentation, manuscript, internal report) |
| Click to enter text. |
| **Data Selection Criteria** |
| **Sex** Choose an item.See all available codes for patient’s sex in the [NAACCR Data Dictionary](https://apps.naaccr.org/data-dictionary/home) |
| **Years of Diagnosis*** The earliest available diagnosis year is 1995.
* It takes approximately two years after the close of a calendar year to collect, quality control, consolidate, and produce analysis files that are considered complete (defined as including at least 95% of all incident cancer cases among Texas residents in a given year).
* Studies requesting the most current information available will receive data that are incomplete and may not pass the CDC’s National Program of Cancer Registries (NPCR), North American Association of Central Cancer Registries (NAACCR), and Surveillance, Epidemiology, and End Results (SEER) Program edit checks.
* In 2020, the impact of COVID-19 on health services and the consequential delays and reductions in cancer screening and diagnosis led to a decline in the 2020 incidence rates for most cancer sites. Because 2020 was a temporary, anomalous year caused by the pandemic, it can bias estimates such as cancer incidence trends that are of substantive interest.
 |
| Begin: Click to enter year. | End: Click to enter year. |
| **Age** |
| Age range: Click to enter range. |
| **Geographic location at time of diagnosis** (select one)[ ]  All of Texas[ ]  Specific location in Texas: Click to enter text. |
| **Cancer Sites**(select one)[ ]  All cancer sites[ ]  Specific cancer sites/types* TCR defines cancers according to the [SEER Site Recode ICD-O-3/WHO 2008 definitions](https://seer.cancer.gov/siterecode/icdo3_dwhoheme/index.html), unless otherwise indicated. List the cancer site groups according to this classification system: Click to enter text.
* If the requested study population is entirely children and adolescents (less than 20 years of age), the [International Classification of Childhood Cancer (ICCC) Recode ICD-O-3/WHO 2008](https://seer.cancer.gov/iccc/iccc-who2008.html) is recommended, but not required. This classification includes benign, borderline, and malignant tumors (behaviors 0, 1, and 3, respectively). If ICCC is used, list the specific extended classification recodes: Click to enter text.
* If SEER site and ICCC-3 recodes do not apply, list the specific [ICD-O-3 topographical codes (site) and morphology codes (histology)](https://apps.who.int/iris/bitstream/handle/10665/96612/9789241548496_eng.pdf): Click to enter text.
 |
| **Behavior** (select all that apply)[ ]  Invasive/malignant cancers [ ]  *In situ* cancers[ ]  Benign/borderline (where reportable) |
| **Additional Selection Criteria** (e.g., limiting dataset by race/ethnicity, stage at diagnosis)Click to enter text. |

|  |
| --- |
| **Special Study Types** |
| Check any of the study types that apply to your project. Complete the corresponding attachment and submit it with this request form.[ ]  Linkage study – [Attachment 1](https://www.dshs.texas.gov/sites/default/files/tcr/data/research/Attachment%201%20Linkage%20Study%20%28Revised%20February%202024%29.docx)[ ]  Patient contact study – [Attachment 2](https://www.dshs.texas.gov/sites/default/files/tcr/data/research/Attachment%202%20Patient%20Contact%20Study%20%28Revised%20August%202023%29.docx)[ ]  Student project – [Attachment 3](https://www.dshs.texas.gov/sites/default/files/tcr/data/research/Attachment-3-Student-Project.docx) |

**Data Item Selection**

* Use the table below to select all data items being requested.
	+ Only data items checked or added to the table will be provided. More rows can be inserted as needed at the bottom of the table.
* Only select data items relevant to your study. The TCR and IRB reviews applications from the perspective of minimum release of data necessary to accomplish study aims.
* Data items marked with an asterisk require specific justification in the table below and in your protocol.
* Confidential data items are in bold. These items require specific justification in the table below and in your protocol.
* Data items requested “for linkage purposes only” will be used in the data linkage process by TCR but will not be provided back to the researcher in the final dataset.
* Please review the [TCR Data Dictionary](https://www.dshs.texas.gov/tcr/data/dictionary.aspx) and [NAACCR Data Dictionary](https://apps.naaccr.org/data-dictionary/home) before selecting data items and submitting the application.
	+ Data items will be labeled using the XML NAACCR ID, when available.
	+ The numbers shown within brackets next to each data item name is the NAACCR item number in the NAACCR Data Dictionary. Not all data items have NAACCR item numbers.

| **TCR Data Item [NAACCR #]**Only select data items relevant to your study. | **Justification/More Information**\*Justification required for data items with an asterisk. |
| --- | --- |
| **Patient Demographics** |
| [x]  | Patient ID Number [20]Sequence Number—Central [380]Tumor Record Number [60]CTC ID (unique tumor identifier) | Included in all datasets |
|[ ]  Sex [220] |  |
|[ ]  Race 1 [160] |  |
|[ ]  Race 2 [161] |  |
|[ ]  Spanish/Hispanic Origin [190] |  |
|[ ]  NHIA Derived Hispanic Origin [191]  |  |
|[ ]  Race-NAPIIA (Derived API) [193] |  |
|[ ]  **Date of Birth [240] \*** | Click to enter justification. |
|[ ]  Year of Birth [240] |  |
|[ ]  Birthplace--State [252] |  |
|[ ]  Birthplace--Country [254] |  |
|[ ]  **Name--Last [2230] \*** | Click to enter justification. |
|[ ]  **Name--First [2240] \*** | Click to enter justification. |
|[ ]  **Name--Middle [2250] \*** | Click to enter justification. |
|[ ]  **Name--Suffix [2270] \*** | Click to enter justification. |
|[ ]  **Addr Current—No & Street [2350] \*****Addr Current--City [1810] \*****Addr Current--State [1820] \*****Addr Current—Postal Code [1830] \*** | Click to enter justification. |
|[ ]  **Telephone [2360] \*** | Click to enter justification. |
| **Characteristics at Diagnosis** |
|[ ]  Addr at DX--State [80] |  |
|[ ]  County at DX Analysis [89] |  |
|[ ]  **Addr at DX--City [70] \*** | Click to enter justification. |
|[ ]  **Addr at DX--No & Street [2330] \*** | Click to enter justification.  |
|[ ]  **Addr at DX--Postal Code [100] \*** | Click to enter justification. |
|[ ]  Rural-Urban Continuum 1993 [3300] |  |
|[ ]  Rural-Urban Continuum 2003 [3310] |  |
|[ ]  Rural-Urban Continuum 2013 [3312] |  |
|[ ]  **Census Tract 2000 [130] \***Census Tract Certainty 2000 [365] | Click to enter justification. |
|[ ]  **Census Tract 2010 [135] \*** Census Tract Certainty 2010 [367] | Click to enter justification. |
|[ ]  **Census Tract 2020 [125] \*** Census Tract Certainty 2020 [369] | Click to enter justification. |
|[ ]  Census Tract Poverty Indicator [145] |  |
|[ ]  **Latitude [2352] \*****Longitude [2354] \***GIS Coordinate Quality [366] | Click to enter justification. |
|[ ]  Texas Public Health Region |  |
|[ ]  Primary Payer at Diagnosis [630] |  |
|[ ]  **Date of Diagnosis [390] \*** | Click to enter justification. |
| [ ]  | Year of Diagnosis [390] |  |
|[ ]  Age at Diagnosis [230] |  |
|[ ]  CoC Accredited Flag [2152] |  |
| **Tumor Characteristics** |
|[ ]  Primary Site [400] |  |
|[ ]  Laterality [410] |  |
|[ ]  Diagnosis Confirmation [490] |  |
|[ ]  Type of Reporting Source [500] |  |
|[ ]  Histologic Type ICD-O-3 [522] |  |
|[ ]  Behavior Code ICD-O-3 [523] |  |
|[ ]  Site Recode ICD-O-3/WHO 2008 |  |
|[ ]  International Classification of Childhood Cancer (ICCC) Recode ICD-O-3/WHO 2008 Extended Classification | Cases diagnosed at <20 years of age. Because ICCC-3 includes benign and borderline tumors for certain site groups, ensure benign/borderline behavior is checked in “Data Selection Criteria” above, if requesting those site groups. |
| [ ]   | SEER Summary Stage Best (one data item that includes the summary stage data item required for that year) [759, 760, 3020, 764] |  |
|[ ]  Tumor Size Summary [756] |  |
|[ ]  EOD Tumor Size [780] |  |
|[ ]  Collaborative Stage (CS)--Tumor Size [2800] |  |
|[ ]  Regional Nodes Examined [830] |  |
|[ ]  Regional Nodes Positive [820] |  |
|[ ]  TNM Clinical Stage [940, 950, 960, 970] | Cases diagnosed 2015-2017. See caution for TNM in the [TCR Data Dictionary](https://www.dshs.texas.gov/tcr/data/dictionary.aspx) |
|[ ]  TNM Pathologic Stage [880, 890, 900, 910] |  |
|[ ]  TNM Clinical Stage [1001, 1002, 1003, 1004] | Cases diagnosed 2018+. See caution for TNM in the [TCR Data Dictionary](https://www.dshs.texas.gov/tcr/data/dictionary.aspx) |
|[ ]  TNM Pathologic Stage [1011, 1012, 1013, 1014]  |  |
|[ ]  TNM Edition Number [1060] |  |
|[ ]  CS--Extension [2810] |  |
|[ ]  CS--Lymph Nodes [2830] |  |
|[ ]  CS--Metastasis at Diagnosis [2850] |  |
|[ ]  CS--Site Specific Factor 1 [2880] | The information recorded and diagnosis years available differ for each site. See the most current version of the "Collaborative Stage Data Collection System" (http://cancerstaging.org). |
|[ ]  CS--Site Specific Factor 2 [2890] |  |
|[ ]  CS--Site Specific Factor 3 [2900] |  |
|[ ]  CS--Site Specific Factor 15 [2869] |  |
|[ ]  CS--Site Specific Factor 25 [2879] |  |
|[ ]  Schema ID [3800] |  |
|[ ]  Brain Molecular Markers [3816] |  |
|[ ]  Breslow Tumor Thickness [3817] |  |
|[ ]  Estrogen Receptor Summary [3827] |  |
|[ ]  Fibrosis Score [3835] |  |
|[ ]  Grade [440] | Cases diagnosed 1995-2017. |
|[x]  Grade Clinical [3843]Grade Pathological [3844] | Cases diagnosed 2018 forward. |
|[ ]  Grade Post Therapy Clin [1068]Grade Post Therapy Path [3845] | Cases diagnosed 2021 forward. |
|[ ]  HER2 Overall Summary [3855] |  |
|[ ]  Microsatellite Instability (MSI) [3890] |  |
|[ ]  Progesterone Receptor Summary [3915] |  |
|[ ]  PSA Lab Value [3920] |  |
|[ ]  Gleason Patterns Clinical [3838] | Cases diagnosed 2021 forward. |
|[ ]  Gleason Patterns Pathological [3839] | Cases diagnosed 2021 forward. |
|[ ]  Gleason Score Clinical [3840] | Cases diagnosed 2021 forward. |
|[ ]  Gleason Score Pathological [3841] | Cases diagnosed 2021 forward. |
|[ ]  Gleason Tertiary Pattern [3842] | Cases diagnosed 2021 forward. |
|[ ]  LDH Pretreatment Lab Value [3932] |  |
| **First Course Treatment \*** |
| TCR treatment data do not undergo the same quality assurance checks as other core data fields. Treatment data often are reported as available and tend to have a higher proportion of incomplete or missing information compared to diagnosis-related or other core data items. Treatment fields may have a value of “none” or “unknown,” both of which do not necessarily indicate an absence of treatment. Therefore, drawing conclusions about the effect of treatment on outcomes is not appropriate. Treatment data may be used for exploratory or supplementary purposes only. Please describe how these important limitations of the treatment data will be incorporated into your study design and/or analysis. **Initial each item listed below if requesting treatment data items:** I have reviewed and considered the limitations of the treatment-related data and will factor these limitations into the study design and/or analysis appropriately. I understand that using TCR data to draw conclusions about the effect of treatment on outcomes is not appropriate. |
|[ ]  **Treatment Initiation Date [1260] \*** | **Provide justification if any treatment data items are requested. Please specifically acknowledge the limitations described above.**Click to enter justification. |
|[ ]  Surgery of Primary Site [1290] \* |  |
|[ ]  Scope Regional Lymph Node Surgery [1292] \* |  |
|[ ]  Surgical Removal of Distal Lymph Nodes or Other Tissue [1294] \* |  |
|[ ]  Reason for No Surgery [1340] \* |  |
|[ ]  Type of Radiation Treatment [1360] \* |  |
|[ ]  Dominant Modality of Radiation [1570] \* |  |
|[ ]  Reason for No Radiation [1430] \* |  |
|[ ]  Phase I Radiation Treatment Modality [1506] \* |  |
|[ ]  Sequence of Radiation and Surgery [1380] \* |  |
|[ ]  Chemotherapy [1390] \* |  |
|[ ]  Hormone Therapy [1400] \* |  |
|[ ]  Immunotherapy [1410] \* |  |
|[ ]  Other Treatment (not surgery, radiation, or systemic therapy) [1420] \* |  |
|[ ]  Hematologic Transplant and Endocrine Procedures [3250] \* |  |

|  |
| --- |
| **Cause of Death and Follow-up** |
|[ ]  **Surv-Date Presumed Alive [1785] \***Surv-Flag Presumed Alive [1786]Surv-Months Presumed Alive [1787]**Surv-Date DX Recode [1788] \***Vital Status Recode [1762] | Only available for survival analysis.Click to enter justification. |
|[ ]  **Date of Last Contact [1750] \*** | Click to enter justification. |
|[ ]  Place of Death--State [1942] |  |
|[ ]  Place of Death--Country [1944] |  |
|[ ]  Vital Status [1760] |  |
|[ ]  Follow-Up Source Central [1791] |  |
|[ ]  Cause of Death [1910] \*ICD Revision Number [1920] | Click to enter justification. |
| **Additional Data Items** |
| List any additional data items relevant for your study (e.g., birth surname and social security number for data linkage conducted by the TCR). Enter the NAACCR data item number and justification. These fields may not have undergone the same quality assurance checks as other core data fields and may have a high proportion of missing or incomplete information.(To add more rows, click the blue plus sign at the bottom right corner of the table.) |
| Click to enter NAACCR data item number. | Click to enter justification. |

|  |
| --- |
| **Dataset Format** |
| Preferred file format for dataset: Choose an item.  |