

## Louisiana Tumor Registry Data Release Policies

### I. Aggregated Data

1. **Definition:** Combines information from multiple cases.
2. **Requirement:**
  - 1) Released to the public upon receipt of written request
  - 2) Data recipient must agree to acknowledge the Louisiana Tumor Registry for the data in any reports and publications
  - 3) Census tract is the smallest unit for which data will be released
  - 4) Counts will be suppressed if there are fewer than 6 cases
  - 5) Rates will be suppressed if based on <16 cases or deaths and/or the underlying population consists of fewer than 20,000 people.
  - 6) Aggregating data with facility identification will be subject to further review by the LTR Research Committee.
3. **Re-release of data:** May be re-released

### II. De-Identified Case-Level Data

1. **Definition:** The LTR follows the HIPAA definition of "de-identified." The following identifiers must be removed for de-identified data release:
  - 1) Name
  - 2) Address (other than state and first three digits ZIP code--if the aggregated ZIP code areas include at least 20,000 people)
  - 3) Census tract or block
  - 4) County/Parish
  - 5) Social security number
  - 6) Day and month of all dates (year is OK)
  - 7) Phone and fax numbers
  - 8) Medical record numbers
  - 9) Identities of physicians, hospitals, or other healthcare providers and facilities
  - 10) Age if it is greater than 89 (these may be aggregated)
2. **Requirements:** Researchers may receive individual de-identified records by:
  - 1) Providing a written proposal/protocol on letterhead (to include a description of physical and policy safeguards to protect data)
  - 2) Providing signed LTR confidentiality agreements from all those who might have contact with the LTR data
  - 3) Obtaining approval by the Director or Deputy Director of Louisiana Tumor Registry or a designated person
  - 4) Data recipient must agree to acknowledge the Louisiana Tumor Registry for the data in any reports and publications.
3. **Re-release data:** Researchers shall NOT re-release data or use the data for any projects other than the approved one.

### III. Limited Data Set

1. **Definition:** The LTR follows the HIPAA definition of a “limited data set.” The following identifiers must be removed for any release of a limited data set:
  - 1) Name
  - 2) Address (other than town or city, state, and ZIP code)
  - 3) Census tract or block
  - 4) Social security number
  - 5) Phone and fax numbers
  - 6) Medical record numbers
  - 7) Identities of physicians, hospitals, or other healthcare providers and facilities
2. **Requirements:** Researchers may receive individual case records in a limited data set by providing:
  - Name of Principal Investigator, with contact information
  - Written proposal/protocol on letterhead, including:
    - o Description of physical and policy safeguards to protect data
    - o Title of the project
    - o Abstract or description of the study
    - o Description of how the LTR data will be used
    - o Name of funding agency and the funding period
    - o Grant/contract number
  - Signature of appropriate data use agreement and/or confidentiality agreements by all researchers who may view the LTR data. These agreements will specify whether or not the researchers plan to contact patients/surrogates.
  - IRB approval, including IRB application, from researcher's institution
  - IRB approval from LSUHSC (LSUHSC employee will serve as PI for LSU IRB purposes) only if LSUHSC investigators will participate in the research.
    - o An IRB review fee will be charged for non-federal grants and contracts.
  - Certificate of completion of the Collaborative Institutional Training Initiative (CITI) training
  - Signature of the LSUHSC Conflict of Interest form
  - Written agreement not to hold the LTR liable in case of a breach of confidentiality (included in LTR confidentiality agreement)

Data recipient must agree to acknowledge the Louisiana Tumor Registry for the data in any reports and publications.

3. **Re-release of data:** Researchers shall NOT re-release data or use the data for any projects other than the approved one. Louisiana data may not be disclosed for any civil, criminal, administrative or other legal proceeding.
4. **Approval of data request:** The LTR Research Committee will review the proposal for compliance with accepted confidentiality procedures and appropriateness of research design.

## IV. Data Linkages

### 1. Introduction:

- 1) The data release policies under this category apply only to researchers who have names and identifiers of patients and request linkages with the LTR database to obtain additional diagnostic, treatment or follow-up information.
- 2) The LTR will perform the linkages and evaluate non-exact matches. Matched cases will be returned to the researchers with the study number as the only identifier. Other identifiers will be removed.
- 3) The LTR will charge for the linkage; fee to be based on the size of the cohort and time spent creating the IRB application, conducting the linkage, manually reviewing matched cases, creating the dataset, and completing the invoice.

### 2. Requirements:

- 1) Name of Principal Investigator, with contact information
  - 2) Written proposal/protocol on letterhead, including:
    - Description of physical and policy safeguards to protect data
    - Title of the project
    - Abstract or description of the study
    - Description of how the LTR data will be used
    - Name of funding agency and the funding period
    - Grant/contract number
    - LTR confidentiality agreements signed by all researchers who may view or have contact with the LTR data.
  - 3) IRB approval, including IRB application, from researcher's institution
  - 4) IRB approval from LSUHSC (LSUHSC employee will serve as PI for LSU IRB purposes) only if LSUHSC investigators will participate in the research.
    - o An IRB review fee will be charged for non-federal grants and contracts.
  - 5) Certificate of completion of the Collaborative Institutional Training Initiative (CITI) training
  - 6) Sign the LSUHSC Conflict of Interest form
  - 7) Written agreement not to hold the LTR liable in case of a breach of confidentiality (included in LTR confidentiality agreement)
  - 8) Provide a sample patient consent form stating that cancer registries or study participants' medical records will be reviewed.
    - o If patients were not informed of medical record review or registry linkage, a data use agreement will be required.
  - 9) Data recipient must agree to acknowledge the Louisiana Tumor Registry for the data in any reports and publications.
- 3. Re-release of data:** Researchers shall NOT re-release data or use the data for any other projects other than the approved one. Louisiana data may not be disclosed for any civil, criminal, administrative or other legal proceeding.
- 4. Approval of data request:** The LTR Research Committee will review the proposal for compliance with accepted confidentiality procedures and appropriateness of research design.

## **V. Requests for Data with Identifiers—With Patient Contact**

### **1. Introduction:**

- 1) Confidential data pertain to individual cases. Data that include any identifier listed in the Definition in Section II, above, are considered confidential.
- 2) Researchers are asking the LTR to identify subjects for their study cohort and plan to contact cohort members.
- 3) The LTR will notify physicians and obtain their consent to contact cases before contacting the patients.
- 4) The LTR will obtain consent from cases or their next of kin before releasing the identities of cases.
- 5) The LTR will expect reimbursement for actual costs pertaining to obtaining physician, patient, and next of kin consent.

### **2. Requirements:**

- 1) Name of Principal Investigator, with contact information
- 2) Written proposal/protocol on letterhead, including:
  - Description of physical and policy safeguards to protect data
  - Title of the project
  - Abstract or description of the study
  - Copy of patient consent form
  - Description of how the LTR data will be used
  - Name of funding agency and the funding period
  - Grant/contract number
- 3) Signature of appropriate data use agreement and/or confidentiality agreements by all researchers who may view the LTR data.
- 4) Signature of the LSUHSC Conflict of Interest form
- 5) IRB approval, including IRB application, from researcher's institution
- 6) IRB approval from LSUHSC (LSUHSC employee will serve as PI for LSU IRB purposes).
  - o An IRB review fee will be charged for non-federal grants and contracts.
- 7) Certificate of completion of the Collaborative Institutional Training Initiative (CITI) training
- 8) Written agreement not to hold the LTR liable in case of a breach of confidentiality (included in LTR confidentiality agreement)
- 9) The LTR will obtain consent from physicians and patients (or next of kin) before releasing patient identifiers to researchers. Researchers will be charged for actual costs to obtain consent from physicians, patients, and next of kin.
- 10) Data recipient must agree to acknowledge the Louisiana Tumor Registry for the data in any reports and publications.

### **3. Re-release of data:** Researchers shall NOT re-release data or use the data for any other projects other than the approved one. Louisiana data may not be disclosed for any civil, criminal, administrative or other legal proceeding.

4. **Approval of data request:** The LTR Research Committee will review the proposal for compliance with accepted confidentiality procedures and appropriateness of research design.

## VI. Requests for Data with Identifiers—No Patient Contact

### 1. Introduction:

- 1) Confidential data pertain to individual cases. Data that include any identifier listed in the Definition in Section II, above, are considered confidential.
- 2) Researchers are asking the LTR to identify subjects for their study cohort and do not plan to contact cohort members.

### 2. Requirements:

- 1) Name of Principal Investigator, with contact information
  - 2) Written proposal/protocol on letterhead, including:
    - Description of physical and policy safeguards to protect data
    - Title of the project
    - Abstract or description of the study
    - Description of how the LTR data will be used
    - Name of funding agency and the funding period
    - Grant/contract number
  - 3) Signature of appropriate data use agreement and/or confidentiality agreements by all researchers who may view the LTR data.
  - 4) Signature of the LSUHSC Conflict of Interest form
  - 5) IRB approval, including IRB application, from researcher's institution
  - 6) IRB approval from LSUHSC (LSUHSC employee will serve as PI for LSU IRB purposes) only if LSUHSC investigators will participate in the research.
    - o An IRB review fee will be charged for non-federal grants and contracts.
  - 7) The LTR must obtain consent from medical facilities if the researcher plans to review medical records or tissue specimens. The researcher will reimburse the registry for the time involved.
  - 8) Certificate of completion of the Collaborative Institutional Training Initiative (CITI) training
  - 9) Written agreement not to hold the LTR liable in case of a breach of confidentiality (included in LTR confidentiality agreement)
  - 10) Data recipient must agree to acknowledge the Louisiana Tumor Registry for the data in any reports and publications.
3. **Re-release of data:** Researchers shall NOT re-release data or use the data for any other projects other than the approved one. Louisiana data may not be disclosed for any civil, criminal, administrative or other legal proceeding.
  4. **Approval of data request:** The LTR Research Committee will review the proposal for compliance with accepted confidentiality procedures and appropriateness of research design.

## VII. Other Louisiana Tumor Registry Policies

- 1. Reimbursement:** The LTR may require reimbursement for labor and other actual costs for any of the above services. In addition, LSU Health Sciences Center charges an IRB review fee for non-federal grants and contracts.
- 2. Cases from the Veterans Administration facilities:** The VA prohibits the release of data with identifiers to researchers.
- 3. Release of Cause of Death:** In general, Cause of Death is not released, and Registry staff will review the source of the information beforehand. Only researchers who have received LSUHSC IRB approval may receive cause of death obtained from the National Death Index (NDI). This information may not be re-released.