Texas Cancer Registry
Guidelines for Research Involving Patient Contact

August 2023

The Texas Cancer Registry (TCR) applies the following programmatic criteria and guidelines for evaluating and approving data requests for research involving patient contact *prior* to the Texas Department of State Health Services (DSHS) Institutional Review Board #1 (IRB) and Research Executive Steering Committee (RESC) submission.

Please note, a copy of these guidelines will be included as an attachment in the required Memorandum of Understanding (after DSHS IRB and RESC review and approval). This will serve as a record that the principal investigator is aware of and agrees to abide by all applicable items below. The principal investigator also assumes responsibility for ensuring all study staff are familiar with these guidelines.

Study and Investigator Requirements

1. If recruiting from multiple sources, TCR patient data cannot be released unless justification is provided showing that TCR as a source of patient data is crucial in meeting recruitment goals and study aims.
2. The principal investigator or a co-principal investigator must have experience conducting patient contact studies.
3. The principal investigator cannot be a student.

Patient Data Limits

4. The IRB application must specify the number of TCR cancer patients the investigators aim to enroll, the expected response rate, and the number of cases requested from TCR.
    a. TCR releases data for up to 1,000 patients at a time. Additional datasets of 1,000 or fewer patients can be provided after TCR reviews the latest study recruitment report, which is required every three months.
5. Once a patient's contact information is released for a particular study, it will not be eligible for release for another study for at least two years to prevent a patient being contacted for multiple studies at one time.
6. TCR will not release contact information for a patient diagnosed within the last eight weeks to ensure the physician has sufficient time to notify the patient of their diagnosis.
7. TCR will not release information on deceased patients for studies requesting contact with next of kin.

General Study Conduct

8. Patient consent to participate must be obtained.
9. Copies of all written materials provided to the patient must be approved by the DSHS IRB.
10. For each patient, TCR recommends no more than:
    a. one introductory pre-letter,
    b. one recruitment letter (see Example Patient Contact Letter),
    c. one follow-up recruitment letter,
    d. three phone calls.
11. If additional recruitment letters or calls are requested, include a detailed justification in Attachment 2: Patient Contact Study.
12. For telephone calls and interviews, verbal scripts must be provided and approved as part of the DSHS IRB and RESC proposal.
    a. The phone script should include confirmation that the caller is speaking to the correct person and an option to opt-out of the call or study.
    b. To avoid disclosure of cancer diagnosis to those other than the intended recipient, voicemail messages should be limited to leaving the caller's name and telephone number. Research staff should also state that the call is related to research they are conducting (but should not specifically mention cancer).
13. Upon receipt of patient contact information provided by TCR, researchers can contact the patient directly, as approved by the DSHS IRB and RESC.
    a. Initial contact with patients must be by mail. TCR recommends sending a brief introductory pre-letter to inform the patient about the study prior to the initial recruitment letter. See more information under the section *Guidelines for Mailed Recruitment Materials*.
    b. Patient recruitment letters must be sent within three months of receiving the patient contact list from TCR. If patient recruitment letters are not sent within three months, letters cannot be sent until TCR receives the study recruitment report and updates the dataset by removing any deceased patients and patients that have requested not to be contacted.
    c. Researchers must allow three weeks for a patient to respond to initial mailing before contacting the patient again.
14. If a patient contacts TCR to be removed from current or future patient contact research studies:

a. The patient will be flagged as a "Do Not Contact" patient in the cancer database.

b. TCR staff will contact the current researcher that the patient has opted out and no additional contact should be made.

15. Researchers must immediately report any complaints regarding the release of patient information to TCR at 512-776-3080 or CancerData@dshs.texas.gov.

d. Never send personally identifiable information via email or email attachment, even if encrypted.

e. Inquiries regarding specific patients must be conducted by either telephone or email using only TCR's patient ID.

Mailed Recruitment Materials

16. Envelopes for any mailed patient pre-letters, recruitments letters and any other materials must be discreet and not indicate that the patient receiving the letter is a cancer survivor. Study names should not be on the envelope.

17. For pediatric patients ages 0-17, letters should be addressed "To the parents/guardians of <patient name>".

18. Each mailing must include a copy of the TCR document "How Did You Get My Name?" (available in English and Spanish).

19. After the introductory pre-letter, each recruitment letter must include:

f. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

g. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the patient is otherwise entitled, and he/she may stop participating at any time without penalty or loss of benefits to which he/she is otherwise entitled.

h. A description of procedures or courses of treatment, if any, that might be advantageous to participants.

i. A description of any reasonably foreseeable risks or discomforts to the participant, as well as a description of any benefits to the participant or to others which may reasonably be expected from the research.

j. Information on exclusion from future patient contact studies must be written in before any institutional contact information:

If you don't want to be contacted for research studies that use information from the cancer registry, contact the Texas Cancer Registry

by email, CancerData@dshs.texas.gov, or phone, 1-800-252-8059 (in Texas) or 512-776-3080. If you have questions about your rights as a research participant, contact the Department of State Health Services Institutional Review Board Administrator at InstitutionalReviewBoard@dshs.texas.gov or 512-776-2202.

k. Contact information for the person(s) who can answer questions about the research and participant rights and who can report a participant's research-related injury.

l. If the research involves more than minimal risk, information on whether any compensation or medical treatments are available if an injury occurs and what they consist of, or where further information can be obtained.

m. A statement that patient data is not being sold to the researchers (i.e., that DSHS and TCR are not being paid or otherwise compensated for the data).

n. See Example Patient Contact Letter

Languages other than English

20. Written patient materials translated into languages other than English must be included in the IRB application. The DSHS IRB requires submission of a Translation Certification Form along with any translated materials.

21. Consider that nearly 30% of Texans over age five speak Spanish as their primary language. Include the following paragraph in Spanish if study materials will not be provided in both English and Spanish:

Le invitamos a participar en un estudio de investigación sobre el cáncer. Tanto si decide participar como si no, su decisión no afectará de ninguna manera la atención médica que usted recibe. Toda la información que nos proporcione es estrictamente confidencial y está protegida por la ley. El equipo de investigadores obtuvo el nombre de usted a través del Registro del Cáncer en Texas (Texas Cancer Registry), un programa del Departamento de Salud y Servicios Humanos (DSHS) de Texas, después de recibir la aprobación del Consejo de Revisión Institucional (IRB). Para participar en este estudio, es necesario que tenga conocimientos de inglés, ya que los materiales solamente están disponibles en este idioma. Si no desea participar, no es necesario que haga nada más al respecto. Si tiene alguna pregunta relacionada con sus derechos como participante en el estudio, comuníquese con el administrador del Consejo de Revisión Institucional (IRB) del DSHS enviando un correo electrónico a InstitutionalReviewBoard@dshs.texas.gov, o llame al 512-776-2202. Si desea que su nombre sea eliminado de todos los estudios futuros de

investigación sobre el cáncer que usen información procedente del registro sobre el cáncer, por favor comuníquese con el Registro del Cáncer en Texas a CancerData@dshs.texas.gov, o llame al 1-800-252-8059 (en Texas) o al 512-776-3080 para avisarnos de su decisión.

Recruitment Report and Study Changes

22. Researchers must submit the following template **every three months** while actively recruiting to CancerData@dshs.texas.gov. At the same time, also email CancerData@dshs.texas.gov a list of patient IDs (only the IDs, with no personally identifiable information) for patients who have contacted you and asked not to be contacted again.

TCR Recruitment Report **IRB # (enter here)** **Date: (enter here)**	*Previous 3 months*	*Entire Recruitment Period*
How many patients were provided to you by TCR?		
How many patients did you contact? Provide separate counts for initial contact and follow ups, if applicable.		
How many patients (or those speaking on behalf of patients) have contacted you, asking not to be contacted again?		
How many patients have enrolled?		

23. If changes are made to any recruitment materials or processes after DSHS IRB and RESC approval, an IRB amendment must be submitted and approved before the changed materials may be used.