Before completing this attachment, review the [Texas Cancer Registry (TCR) Guidelines for Research Involving Patient Contact](https://www.dshs.texas.gov/tcr/data/patient-contact-studies.aspx).

## **Adherence to Guidelines**

Initial each item listed below to confirm you will adhere to the following guidelines:

|  |  |
| --- | --- |
|        | TCR as a source of patient data is crucial in meeting recruitment goals and study aims. |
|        | The principal investigator (PI) or a co-PI has experience conducting patient contact studies and is not a student. |
|       | The number of TCR cancer patients the investigators aim to enroll, expected response rate, and number of cases requested from TCR will be included in the application. TCR releases data for up to 1,000 patients at a time. |
|        | Patient consent will be obtained. |
|       | Initial contact with patients will be by mail and will include all components outlined in [TCR Guidelines for Research Involving Patient Contact](https://www.dshs.texas.gov/texas-cancer-registry/data-requests-tcr/research-data/patient-contact-studies). |
|        | Patient recruitment letters will be sent within three months of receiving the patient contact list from TCR. |
|        | Patients will be given three weeks to reply to the initial recruitment letter before being contacted again. |
|        | All complaints regarding the release of patient information will be reported within two business days to TCR. |
|        | A recruitment report will be submitted to TCR every three months. |
|       | If changes are made to any recruitment materials or processes, a DSHS IRB amendment must be approved before the changed materials or processes may be used. |
|       | [TCR Guidelines for Research Involving Patient Contact](https://www.dshs.texas.gov/texas-cancer-registry/data-requests-tcr/research-data/patient-contact-studies) has been reviewed in full and the research team will adhere to them. |

## **Study Recruitment**

Enter the following information about patient accrual.

|  |  |  |
| --- | --- | --- |
|        |  | Number of TCR patients you want to enroll |
|       % |  | Expected patient response rate |
|        |  | Number of patients requested from TCR (based on figures above) |

## **Proposed Recruitment Schedule**

Check all forms of contact you will use to recruit patients. Fill in the maximum number of times you will contact a patient via this contact method before they are considered a non-responder. If your contact attempts exceed the TCR guidelines, provide justification.

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Contact** | **TCR Guidelines** | **Maximum attempts for this study** | **Justification for exceeding TCR guidelines** |
|[ ]  Introductory pre-letter | 1 Introductory pre-letter |       |        |
|[ ]  Recruitment letter | 1 Recruitment letter |       |       |
|[ ]  Follow-up recruitment letter | 1 Follow-up recruitment letter |       |       |
|[ ]  Telephone | 3 Calls |       |       |

## **Required Documents**

List the file names for each of the following required documents you are submitting.

|  |  |
| --- | --- |
| Introductory pre-letter |        |
| Recruitment letter(s) |        |
| Follow-up recruitment letter(s) |       |
| Patient consent form(s) |        |
| Phone script(s), if applicable |        |
| Voicemail script(s), if applicable |        |
| Translation certification form, if applicable |        |

Examples of required documents for patient contact studies are located on the TCR website:

* [Example Patient Contact Letter](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.dshs.texas.gov%2Fsites%2Fdefault%2Ffiles%2Ftcr%2Fdata%2Fresearch%2FExample-Patient-Contact-Letter.docx&wdOrigin=BROWSELINK)
* [How Did You Get My Name? (English)](https://www.dshs.texas.gov/sites/default/files/tcr/data/research/HDYGMN-Q-and-A.pdf)
* [How Did You Get My Name? (Spanish)](https://www.dshs.texas.gov/sites/default/files/tcr/data/research/HDYGMN-Spanish.pdf)