UT Health San Antonio (UTHSA)

**Institutional Inactivation Form – UTHSA IRB Exempt Research and External Studies**

|  |
| --- |
| **\*\*\* Important Reminder when inactivating your study \*\*\***1. The study records must be stored in a secure location according to the UT Health policy on [record retention](http://library.uthscsa.edu/rrs/recordrrs.php).
2. Continued analysis of permanently de-identified data (per HIPAA) by the researcher is authorized. Identifiable data or specimens obtained as part of this research cannot be used in other research without the approval of the IRB. Maintaining data or specimens for use in future research is considered banking (repository) and requires IRB approval.
 |

**Date:**

| **UTHSA Tracking Number**       |
| --- |

| 1. **Title**
 |       |
| --- | --- |

| 1. **Principal Investigator**
 |
| --- |
| First Name\* |       | Last Name\* |       |
| Organization\* |       | Department\* |       |
| Degree(s)\* |       | Cell Phone or Pager |       |
| Preferred email\* |       | Office Phone\* |       |

\* Required Fields

| **PI’s Point of Contact** |
| --- |
| First Name\* |       | Last Name\* |       |
| Office Phone\* |       | Cell Phone or Pager |       |
| Preferred email\* |       |

\* Required Fields

| 1. **Study Status**
 |
| --- |
| [ ]  This is an external IRB study and a copy of the external IRB inactivation letter or site removal letter is **attached**; **OR**  |
| [ ]  This is a UTHSA IRB exempt study and data/specimen analysis has been completed; **OR**[ ]  This is UTHSA IRB exempt study and data/specimen analysis is limited to de-identified data only. The identifiable data/materials and key to any codes have been archived in a secure location.**If you are still analyzing identifiable data/specimens, you cannot inactivate your study at this time.** For questions, contact the OCR at 210-567-8555. |

|  |
| --- |
| **4. Reporting Requirements** Did any of the following events occur?  *Select all that apply.* |
| [ ]  Failure to follow institutional requirements (examples): * Personnel engaging in research activities without prior approval
* Data incidents involving private identifiable information
* Any issues involving a HIPAA waiver/authorization
* Any issues involving a conflict of interest (COI)
* Any issues involving local safety committee approvals
 | [ ]  Suspension or termination of site by Sponsor |
|  [ ]  OHRP Determination Letter |
|  [ ]  FDA Warning Letter, FDA 483 Inspection Reports or FDA Restrictions placed on an IRB or Investigator |
| [ ]  Compliance actions from sources other than UTHSA |
| [ ]  Press coverage of a negative nature involving the institution |
| [ ]  Arbitrations or settlements initiated related to human subject protections | [ ]  Other:       |
| Did items selected above get reported to the institution?  |
| [ ]  N/A | No items selected above. |
| [ ]  Yes  | No further action required. |

|  |
| --- |
| **5**. **ClinicalTrials.gov**  |
| [ ]  Not applicable. (*My study is* ***not*** *registered with UTHSA clinicaltrials.gov.)* |
| [ ]  This study is registered on UTHSA clinicaltrials.gov.  |
|  | [ ]  | I have updated the contact information and responsible party email address in ClinicalTrials.gov.  |
|  |  | [ ]  PI contact information has not changed.[ ]  PI contact information has changed or will be changing to: Phone:       Email:       |
|  | [ ]  | I am aware that I am still responsible for maintaining and updating the ClinicalTrials.gov record for this study and reporting results. |
|  | [ ]  | I am aware that there are new requirements to post a protocol and statistical analysis plan on all applicable Clinical Trials with a primary completion date on or after January 18, 2017 on ClinicalTrials.gov. |

|  |
| --- |
| **6**. **Sponsor Investigator Studies** |
| [ ]  Not applicable. *(This study does not have an IND or IDE held by a local investigator.)* |
| [ ]  Yes. *(This study has an IND or IDE held by a local investigator.)*  |
|  | [ ]  | This is a cancer center study. Local monitoring is conducted by the Cancer Center. |
|  | [ ]  | This is a non-cancer center study. *Attach any study monitor report(s) for this period.*  |

|  |
| --- |
| **7**. **Drug or Device Storage**  |
| [ ]  Not applicable.  *(This study does not have an OCR approved drug or device storage Standard Operating Procedure.)* |
| [ ]  Yes. *Provide OCR approval number:*  |  |

|  |
| --- |
| **8**. Is the **PI leaving the institution** and planning to transfer research data to a new institution? |
| [ ]  No. |
| [ ]  Yes, What type of data will the PI be transferring?  |
|  | [ ]  De-Identifiable Data [ ]  Identifiable Data |

**COMPLETE THE NEXT TWO QUESTIONS FOR CLINICAL TRIALS ONLY**

[ ]  Not a clinical trial – **do not complete items below**

|  |
| --- |
| **9. Subject Enrollment** (from all study sites) |
| Since the start of the study, how many subjects have you enrolled (consented) or included in research (waived consent):  |

|  |
| --- |
| **10.** To assist research administration with **improving the conduct of clinical trials** at UTHSC, please provide feedback on the following by **selecting all that apply:** [ ]  No concerns to report  |
| [ ]  Difficulties recruiting eligible subjects or collecting required data, specify: [ ]  Insufficient patient population. Please provide details:       [ ]  Inability to access patient population. Please provide details:       [ ]  Institutional resources not available. Please provide details:       [ ]  Other. Please provide details:       |
| [ ]  Inability to obtain institutional approval at an affiliate site. Please provide details:       |
| [ ]  Insufficient staff to complete study. Please provide details:       |
| [ ]  Loss of funding or inadequate funding. Please provide details:       |
| [ ]  Site or study closed by sponsor. Please provide details:       |
| [ ]  Other:       |