UT Health Science Center San Antonio

**Final Report**

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| **Request for Inactivation** |

Using this form – To check the checkboxes, click once on the box. To enter text in the text boxes, click once on the gray box and then type your response.

Form Instructions:

* Use this form to inactivate the IRB approval for this research. Submit within 30 days after completion of the study.
* Only the Principal Investigator may sign Form A-1. Sub Investigators or other signatures are NOT acceptable.
* This form should be submitted after the final (close out) site visit by the study sponsor (as applicable)
* This final report form should not be submitted if federal funding is still being obtained (e.g., grant still active).
* Submit the following: 1) a signed Form A-1, 2) all applicable attachments (as directed on the form), 3) an electronic copy of this form and any applicable attachments**.** You should also retain one copy of the submission package for your files.
* All data and study records must be retained for a minimum of six years after the completion date. Longer recordkeeping periods may be imposed by UTHSCSA or other agencies (check applicable guidance).

**Study Title:**

**1. Date:**

**2. Name of Principal Investigator (PI):**  *(This is the primary contact information used by the IRB. Indicate where mail can most reliably reach the PI. If research is part of a multi-center study, the PI listed here should be the investigator responsible for the research conducted locally.)*

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| PI Name *(Last Name, First Name, MI):* | |  | |
| Employer(s): *Example: UTHSCSA 50%, or VA 50%)* | | |  |
| Department: |  | | |
| Room # & Bldg: |  | | |
| Mail Code #**:** |  | | |

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| **3. Additional Contact Information** | | |  | |  | | |  | |
| PI’s Telephone#: |  | | | | PI’s Pager Number: | | |  | |
|  | | | | | | | | | |
| PI’s e-mail address: |  | | | PI’s FAX Number: | | |  | | |
|  | | | | | | | | | |
| PI’s Position Title: |  | | | | | | | | |  |
|  | | | | | | | | | |
| PI’s Point of contact name & e-mail: | |  | | | | Point of Contact Phone Number: | | |  |

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| **4**. During this review period, **have there been any changes**, no matter how minor, to any part of this research project, including the IRB approved forms? | | | |
|  | **No.** Go to Question 5. | | |
|  | **Yes.** *If yes, select one* | | |
|  | All changes implemented have been previously reported to and approved by the IRB. | |
|  | The changes described below have been implemented but were not submitted to or approved by the IRB. | |
| a. Give a brief description of the change(s) made | b. Explain why IRB approval was not obtained prior to making the change(s) |
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**Locally Enrolled Subject information**

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| NOTE: You should compare all information entered in this report with what has been previously reported to the Board. If you discover that there are discrepancies with or errors in previously reported information, please attach a separate cover letter explaining the differences. |

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| **5**. Choose the statement that best describes the **human research activities** being performed. *Select only one.*  **This study**: | | |
|  | Involves interacting/intervening with living individuals for research purposes | *Answer all questions in item 6, below* |
|  | Is limited solely to use of identifiable private information, such as data, records, specimens, etc. (Does not involve interacting with living individuals for research purposes) | *Answer questions in item 6 below--****some questions may not be applicable*** |

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| **6**. In order to **inactivate** IRB approval, the following must be true: *Confirm by checking the appropriate response* | | | |
| **Research activities related to human subjects and identifiable private information** | **True** | **False** | **N/A** *and provide reason*  *(edit text as needed)* |
| Enrollment of new subjects is permanently closed |  |  | Does not involve subjects |
| Data, private information, and/or clinical specimens are no longer being collected for research purposes (including long term follow up) |  |  |  |
| Subjects are no longer being treated under the research protocol (includes no plan for future research treatment) |  |  | Does not involve subjects or treatment |
| Research assessments or procedures are no longer being performed (includes no plan for future research procedures) |  |  | Does not involve subjects |
| Federal research funding for this study is closed |  |  | Does not involve federal funding |
| If this is a multi-center study where UTHSCSA is the study operations center or the UTHSCSA investigator is the Lead Investigator, is the study closed at all participating sites? |  |  | Not multi-center study, or UTHSCSA is not operations center / Lead PI |
| Data/specimen analysis has been completed locally  **or**  If analysis continues locally, the identifiable data/materials and key to any codes have been archived in a secure location. Any continued analysis will only use data or specimens that the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the information or specimens pertain. |  |  |  |
| If you answered “false” to any of the questions above, **you cannot inactivate your IRB approval at this time 🡪** Contact the IRB Office at 567-8250 if you have questions. | | | |

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| **7**. **Number of subjects** (or records/specimens) **accrued (from all relying study sites which have deferred IRB review to UT Health San Antonio).**  Note for studies only accruing data/specimens – for this section, obtaining an individual’s information or specimens is considered enrolling subjects. Please include these numbers in the table below. | |
| **Local**  *(at this site)* | **Total Number** |
| **A.** What is the total number of subjects **authorized/approved** by IRB? |  |
| **B.** Since last IRB review, how many subjects have you either:   * Enrolled (consented); or * Included in research (waived consent) |  |

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| **C.** Since the start of the study, how many subjects have you:   * Enrolled (consented); or * Included in research (waived consent) |  |

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| **8A**. **Number of Veteran subjects** (or records/specimens) **accrued.** | | | | | |
|  | Check here if study does not involve South Texas Veteran’s Healthcare System (STVHS)  Skip to Question 8B. | | | | **Number** |
| **i.** How many VETERAN subjects have been enrolled or VETERAN subject charts reviewed since this project was initiated? | | | | |  |
| **ii.** Is this project approved to enroll NONVETERAN subjects at the STVHS Site? | | | | |  |
|  |  | **Yes** If Yes, Complete Question 8B.iii. |  | **No** If No, Skip to Question 8B. |  |
| **iii.** How many NONVETERAN subjects have been enrolled at the STVHS site since this project was initiated? | | | | |  |
| **iv.** Are VETERAN/NONVETERAN subjects that were enrolled at the STVHCS currently being followed? | | | | |  |
|  |  | **Yes** |  | **No** |  |

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| **8B. If this study is a multi-site study, in which the relying site has ceded IRB review to UT Health San Antonio, complete this item for each relying site.** *[Copy and paste for each site.]*  **Indicate the Number of subjects (or records/specimens) accrued.** | | |
|  | Check here if study does not involve other study sites  Skip to Question 9. | **Number** |
| **Site name🡪** | | |
| Insert the number of subjects which have been enrolled or the number of charts reviewed since this project was initiated? | |  |

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| **9. Major Categories of Withdrawals**  *(at this site since the last IRB review)* | | | **Total Number** |
|  | Check here if study only involves accruing data/specimens (does not involve interacting with subjects). Skip to Question 10. | |
| **E.** How many subjects were Screen failures *(signed consent & completed only part or all of screening)?* | | |  |
| **F.** How many subjects discontinued due to an Adverse Event (AE), *except death*? | | |  |
| **G.** How many subjects withdrew by their choice? | | |  |
| **H.** How many subjects were withdrawn by PI (i.e., subject non-compliance, disease progression, etc.)? | | |  |
| **I.** How many subjects died during their participation period? | | |  |
| **Total Since Study Started** | | | |
| **J.** How many subjects have completed the study **since the study started**? | | |  |
| **K.** Total number of withdrawals **since the study started**. | | |  |
| **Detailed description** of the reason for **subject withdrawal** noted above *since the last IRB review*. | | | |
|  | **N/A** – No subjects have withdrawn from the research since the last IRB Review. Go to Question 10. | | |
| **Detailed Description of the Reason for Withdrawal** | | **Total number per reason** | |
| *For example, for subjects who discontinued due to AE – describe the actual AE(s) experienced that lead to withdrawal; for those who withdrew by choice, describe their stated reason(s)* | | *How many subjects withdrew for each reason listed?* | |
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**Consent**

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| NOTE: Please enter information related to the consent process and documentation. |

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| **10**.Does this study involve **obtaining consent**? | | | | |
|  | No. Consent was waived by the IRB for all subjects participating. Go to Question 11. | | | |
|  | Yes. **If yes,** answer the following questions: | | | |
|  | **Yes** | **No** | **N/A**  No subjects enrolled |
| A. Was consent obtained for all subjects enrolled **since the last IRB review**? |  |  |  |
| If **No, explain here 🡪** | | | |
| B. Did all subjects enrolled **since the last IRB review** receive a copy of the signed consent form? |  |  |  |
| If **No, explain here 🡪** | | | |

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| **11.** Is this study approved for **surrogate consent** of adult subjects? | | | | | |
|  | No. Go to Question 12. | | | | |
|  | Yes. **If yes,** answer the following questions: | | | | |
|  | | **Number** | | **N/A**  No subjects enrolled |
| How many subjects were enrolled by surrogate consent **since the last IRB review?** | |  | |  |
| How many subjects who were enrolled by surrogate consent have subsequently **consented to continue** in the study since the last IRB review? | |  | |  |
| How many subjects who were enrolled by surrogate consent have subsequently **decided not to continue** in the study since the last IRB review? | |  | |  |
| Describe the reasons why subjects enrolled by surrogate consent later **did not agree to continue in the study**. | | | | |
| **Describe here 🡪** | | | | |
|  | **Yes** | | **No** | **N/A**  No subjects enrolled |
| Did the surrogate receive a copy of the signed consent form? |  | |  |  |

**Summary of Study**

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| **12**.Summary of**Study** |
| Summarize your study’s **success** toward achieving the objectives of the study. *If this study is being inactivated due to premature closure of the study provide details below.* |
| **Describe here 🡪** |

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| **13**. **Subjects' response** to the study since the last IRB review. Please describe how subjects have responded to and tolerated their participation in this research project. ***Your******Answers should be substantive.*** | | | | | |
| Were any subjects actively participating in this study during the period of time since the last IRB review?  *Choose one* | | | | | |
|  | **N/A** – Study only involves accruing data/specimens (does not involve interacting with subjects). Go to Question 14. | | | | |
|  | **No.** Go to Question 14. | | | | |
|  | **Yes.** If **Yes**, answer the following questions: | | | | |
| **(a)** How has the study **affected** the subjects since the last IRB review? | | | | |
| **Explain here 🡪** | | | | |
| **(b)** Have subjects had any **comments or complaints** about the study since the last  IRB review? |  | **Yes** |  | **No** |
| If **yes**, provide details here**🡪** | | | | |

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| **14**. Were all **study procedures** conducted as described in the protocol? | |
|  | **Yes.** |
|  | **No.** |
| If **No**, **explain here 🡪** |
|  | **Not applicable.** |
| **If N/A.****explain here 🡪** |

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| **15**. Is this a **multi-center study** where the UTHSCSA IRB is the reviewing IRB for the study operations center? | | | | | |
|  | **No.** | | | | |
|  | **Yes.** Have there been any oversight problems at the satellite study sites? |  | **Yes** |  | **No** |
| **If yes, explain here 🡪** | | | | |

**Adverse Events, Other (non-AE) Problems**

**and**

**Unexpected Problems Involving Risks to Subjects and Others (UPIRSO)**

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| NOTE: Review your study records related to adverse events, other (non-AE) problems and UPIRSOs since the last IRB review and also for the entire study to answer the following questions. *If this inactivation is due to premature closure of the study evaluate for a possible UPIRSO and submit a prompt report if applicable*. |

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| **16**. Taking into consideration all safety-related information, have any adverse events occurred since the last IRB review? | | |
|  | **No.** Skip to Question 19 | |
|  | **Yes.**  **If yes**, have the adverse events been of the nature and occurred at the frequency and severity that were anticipated?  *(in order to determine frequency, you should consider all AE’s that have occurred since the study started)* | |
|  | Yes, the adverse events have occurred as **anticipated**. Skip to Question 19 |
|  | No, there have been **unanticipated** adverse events. Go to Question 17. |

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| **17**. Were any of the unanticipated adverse events identified in question 16, at least possibly related to the research? | | |
|  | **No.** Skip to Question 19 | |
|  | **Yes.** There have been unanticipated AEs that are at least possibly related.  **If yes**, have the unanticipated and possibly related adverse events been **serious or do they suggest a greater risk than previously known**? | |
|  | Yes. Go to Question 18 |
|  | No. Skip to Question 19 |

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| **18**. Were all the unanticipated adverse events that were at least possibly related and were either serious or suggest a greater risk identified in question 17, previously reported to the IRB as possible Unanticipated Problems Involving Risks to Subjects or Others (UPRISOs)? | | | |
|  | **No.**  **If No**, explain why prompt reporting was not accomplished. | | |
| A. | **Explain here 🡪** | |
| B. | Attach a new “Notification of Possible UPIRSO” to this progress report. Go to Question 19 | |
|  | **Yes.** List the UPIRSO’s previously reported below. Then Go to Question 19 | | |
| **Date Reported** | | **Brief description of the UPIRSO** |
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| **19**. Have there been any other problems that were not adverse events since the last IRB review? | | |
|  | **No.** Go to Question 21 | |
|  | **Yes. If yes**, were the non-AE problems of a nature that may have placed subjects (or others) at **greater risk**? *(For example the loss of confidential data, dosing error with no detectable harm, etc.)* | |
|  | Yes, the non-AE problems may have placed subjects at greater risk. Go to Question 20 |
|  | No. Go to Question 21. |

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| **20**. Were all the non-AE problems identified in question 19, previously reported to the IRB as possible Unanticipated Problems Involving Risks to Subjects or Others (UPRISOs)? | | | |
|  | **No. If No**, explain why prompt reporting was not accomplished. | | |
| A. | **Explain here 🡪** | |
| B. | Attach a new “Notification of Possible UPIRSO/ Non-Adverse Event” to this progress report. Go to Question 21 | |
|  | **Yes.** List the non-AE UPIRSO’s previously reported below. Then Go to Question 21 | | |
| **Date Reported** | | **Brief description of the non-AE UPIRSO** |
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| **21**.  **PI Responsibilities After Inactivation** | |
| As the Principal Investigator, I understand the following: | |
|  | Inactivation means that the UTHSCSA IRB approval to conduct research has ended. |
|  | Storage of study records, including identifiable private information is authorized. The study records must be stored in a secure location. See UTHSCSA’s policy on record retention. |
|  | 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. |

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| **22**. **Repository Information**  *Note: Data management centers (data centers) and human specimen repositories (e.g., registries, banks, or libraries) are used to store data and/or specimens for future research use.* | | | | | | |
|  | | | | | **Yes** | **No** |
| Does this study **collect** specimens/data for inclusion in a Repository or data center? | | | | |  | Skip to question 23 |
| Is the specimen repository or data center located at an institution under the oversight of the UTHSCSA IRB? | | | | |  | Skip to question 23 |
| Is the repository / data center established and operations approved under this protocol? | | | | |  | Skip to question 23 |
| Since IRB approval is required to operate a research repository / data center, what is the disposition plan for the repository materials? | | | | | | |
| **Select option** |  | | | | |
|  | Transfer repository materials to another  IRB approved repository. **Insert IRB # here 🡪** | |  | | |
|  | Destroy the repository materials. | | | | |
|  | Other. **Provide an explanation here 🡪** |  | | | |

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| **23**. Is there any **new information** that should be communicated to the subjects? (e.g., new risks, information related to possible benefits, etc.) | |
|  | No. |
|  | Yes. |
| **Provide a summary and implications for subjects** |
| Summarize here🡪 |

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| **24**. Is this final report being submitted after the **IRB expiration date**? | | | | | |
|  | **No.** | | | | |
|  | **Yes.** Has there been any research activity (e.g., enrollment, data collection, research procedures or treatments, use of identifiable research data, etc.) after the expiration date? |  | **Yes** |  | **No** |
| **If yes, explain here 🡪** | | | | |

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| **25**. Is this study approved at other UTHSCSA IRB Affiliated institutions?  [[South Texas Veterans Health Care System](https://www.southtexas.va.gov/Research/Documents/RequestInactivationResearchProtocol.doc), [University Health System](http://hr.universityhealthsystem.com/research/Research_Department_Home.htm), [Christus Santa Rosa Health Care](http://www.christussantarosa.org/)] | |
|  | No. |
|  | Yes. |
| **If yes, notify the research office of the affiliated institution that the study is being inactivated** (links provided above). Additional documentation may be required by the institution. |
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| **26**. Will the PI be leaving the institution and transferring research data to a new institution? | | | | | |
|  | No. | | | | |
|  | Yes. | | | | |
| What type of data will the PI be transferring? | | | |
|  | Identifiable Data |  | De-Identifiable Data |

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| **27.**  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.* |

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| **28**. Which items are being **attached** to this Progress Report? *Check all that apply.* | |
|  | Form A-1, Multipurpose Signature Assurance Sheet - **Required** |
|  | Final report. to funding agency |
|  | DSMB report or independent medical monitor report |
|  | Sponsor reports or notifications |
|  | New information on risks or benefits |
|  | Notification of Possible UPIRSO form |
|  | Form X – Conflict of Interest |
|  | Report of Noncompliance |
|  | Approval to Transfer Research Data |
|  | Publication(s) or meeting proceedings |
|  | Monitoring Report for Local Sponsor Investigator Study (only for *studies with an IND or IDE held by a local investigator)* |
|  | Other: (describe) |

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

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

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| **29.** Clinical Trials | |
|  | Not applicable. (*My study is* ***not*** *registered with UTHSA clinicaltrials.gov.)* |
|  | My study is registered with 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. |

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| **30.** 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: |

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| **31**. **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:* |  |