UT Health Science Center San Antonio

**Progress Report**

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| **Request for re-approval** |

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.*.*

Do not delete any tables on this form. Review the [IRB policy on Continuation Review](https://www.uthscsa.edu/sites/default/files/Services/forms/irb_continuation_review_policy.pdf) (request for re-approval).

**Study Title:**

**1. Date:**

**2. Name and Address 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, VA)* | |  |
| Department: |  | |

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| **3. Additional Contact Information** | | |  | |  | | |  | |
| PI’s Telephone#: |  | | | | PI’s Pager Number: | | |  | |
|  | | | | | | | | | |
| 1. PI’s e-mail address: |  | | |  | | |  | | |
|  | | | | | | | | | |
| 1. PI’s Point of contact name & 2. 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 6. | | | |
|  | **Yes.** *If yes,* ***select******one.*** | | | |
|  | All changes implemented have been previously reported to and approved by the IRB. Complete question 5 | |
|  | Some changes have been **implemented** but were not submitted to or approved by the IRB. Describe below | |
|  | 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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| **5**. Provide a summary of **previously approved amendments** or modifications since the last review using the table below: *(do not include pending or recently submitted amendments (not yet approved)* | |
| **Date on the amendment form** | **Brief Summary of the Approved Changes** |
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| **6**. Minor modifications are allowed as part of this progress report. The changes allowed are limited to:  **a)** The names and contact information provided in previously approved consent form(s);  **b)** Addition of new wording from the current HSC or VA consent template to consents that are based on older versions of the template; and/or  **d)** Indicate this as a multi-center study that the sponsor has authorized competitive local enrollment.  **[Submit a separate amendment for all other modifications]**  **Have you included any of these minor modifications with this progress report?**  *(All other modifications must be submitted as a separate amendment request)* | | | | | | |
|  | **No.** Go to Question 7. | | | | | |
|  | **Yes.**  Choose from the options listed below and check all that apply. | | | | | |
| **Minor Modifications Request** *(Amendment Form Not Required)* | | | | | |
|  | **Updated study personnel** (not including the PI). Submit [Personnel Changes via Email](https://www.uthscsa.edu/vpr/services/personnel-change). | | | | |
|  | | Does the change in personnel require a revised consent form? |  | **Yes -** attached a revised consent form (track changes) |  | **No** |
|  | **Update name(s) and/or contact information in a consent form**.  *Attach a revised consent form (track changes)*  Summarize changes here **🡪**: | | | | |
|  | **Update a consent form with new IRB approved wording from the latest consent template**.  *Attach a revised consent form (track changes)*  Summarize changes here **🡪**: | | | | |
|  | **Update this multi-center study’s local enrollment number to indicate that the sponsor has authorized** [**competitive enrollment**](https://www.uthscsa.edu/vpr/services/glossary#Competitive-Enrollment).  *Total number of subjects enrolled study-wide is unchanged, however local site has been authorized by the sponsor to enroll more subjects than the original target number* | | | | |

**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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| **7**. Choose the statement that **best** describes the human research activities being performed. *Select only one*.  **This study**: | | |
|  | Is limited solely to use of identifiable private information (data, records, specimens, etc.) (Does not involve interacting with living individuals for research purposes) | **GO TO ITEM 8A** |
|  | Involves interacting or intervening with living individuals for research purposes | **GO TO ITEM 8B** |

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| **8A**. **Current status - for research that does not involve interaction or intervention with living individuals**  Researchers do not intervene or interact with living individuals. This study only obtains private identifiable  information (e.g., data, records), or specimens from the source that originally collected the materials. | | | |
| **(i). Are you currently obtaining or receiving new private identifiable information or specimens?** *Select one* | | | |
|  | No. New private identifiable information or specimens will no longer be obtained or received (collecting activities are permanently closed) | |
|  | No. We have temporarily halted any collecting activity to acquire private identifiable information or specimens (temporarily halted) | |
|  | Yes. Private identifiable information or specimens are still being obtained/received or will be obtained in the future **[GO TO ITEM 9]** | |
| **(ii). Are you currently using private identifiable information or specimens?** *Select one* | | | |
|  | | No, we have completed all use of private identifiable information or specimens or are only using information or  specimens that the investigator cannot readily ascertain the identity of the individual(s) to whom the materials  pertain. **[GO TO ITEM 9]** |
|  | | No, we have temporarily halted use of private identifiable information or specimens (temporarily halted)  **[GO TO ITEM 9]** |
|  | | Yes, private identifiable information or specimens are still being used or will be used in the future **[GO TO ITEM 9]** |

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| **8B. Current status - - for research that involves interaction or intervention with living individuals**  What is the current status of local research activities related to human subjects and identifiable private information? | | |
| **(i). Recruitment of new subjects**  *Select one* | | |
|  | **Not yet recruiting** – participants are not yet being recruited **[GO TO ITEM 9]** |
|  | **Recruiting** – participants are currently being recruited through open recruitment |
|  | **Enrolling by invitation only** – participants are currently being (or will be) selected from a pre-determined  population (i.e., not open recruitment, may be enrolling from another study). |
|  | **Temporarily closed to enrollment** – enrollment is halted, but will potentially resume |
|  | **Permanently closed to enrollment**– enrollment in the study is complete and will not resume |
| **(ii). Have any subjects been enrolled (consented) locally?** *Select one* | | |
|  | No If no **[GO TO ITEM 9]** |
|  | Yes *If yes complete information below* |
| **(iii).** Status of research-related **interactions or interventions**  *(i.e., research procedures or components listed in Form C*  *Select one* | | |
|  | Status 1 - Research procedures (any interaction or intervention for research purposes) are currently being performed involving at least one subject |
|  | Status 2 - Research procedures (any interaction or intervention for research purposes) are not currently being performed involving at least one subject. However, we plan on performing research procedures (interactions or interventions) in the future |
|  | Status 3 - Research procedures (any interaction or intervention for research purposes) are not currently being performed involving at least one subject and we will not be performing research procedures (interactions or interventions) in the future |
| **(iv). Does the remaining research activity only involve:**   * minimal risk **interactions** with the subjects **or** * **interventions** that would be performed as part of routine practice **or** * data collection from record review? | | |
|  | Yes |
|  | No |
| **(v). Local analysis of identifiable data** Select one | | |
|  | A. We have not started data analysis |
|  | B. We are still performing analysis of identifiable data |
|  | C. We will not be performing data analysis locally, have completed data analysis or are performing analysis only using that the investigator cannot readily ascertain the identity of the individual(s) to whom the materials pertain. |

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| **9A**. **Number of subjects** (or records/specimens) **accrued (from all study sites).**  **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** |
| **i.** What is the total number of subjects **authorized/approved** by IRB?  *[If competitive enrollment previously approved by IRB, insert “CE” here]* **→** |  |
| **ii.** On your **last progress report** – how many total subjects were reported as enrolled and consented**?**  *[If this is the first progress report, insert N/A]* |  |
| **iii.** **Since last IRB review,** how many subjects have you either:   * enrolled (consented); or * included in research (waived consent) |  |
| **iv.** **Since the study started,** how many subjects have you either:   * enrolled (consented); or * included in research (waived consent)   Hint: If this is the first progress report, 9iv **=** 9iii. If not the first progress report, 9iv **=** 9ii **+** 9iii  Hint 9iv **=** 9v **+** 9vi **+** 9vii |  |
| **v.** How many subjects are **currently** active (includes long term follow up)? |  |
| **Total Since Study Started** | |
| **vi.** How many subjects have completed the study **since the study started**? |  |
| **vii.** Total Number of Withdrawals **since the study started.**  Hint: vii **=** 10i **+** 10ii **+** 10iii **+** 10iv **+** 10v **+** 10vi *(below)* |  |

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| **9B**. **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 9C.** | | | | **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 9B.iii.** |  | **No If No, Skip to Question 9C.** |  |
| **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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| **9C. 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 10.** | **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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| **10**. **Withdrawals at this site (from all study sites).** | | | |
|  | | | **Number** |
| **i.** **On your** **last progress report** – how many total subjects were reported as withdrawn *since the study started***?**  *[If this is the first progress report, insert N/A]* | | |  |
| **ii.** Since your last IRB review, how many subjects were **Screen failures** *(signed consent & completed only part or all of screening)?* | | |  |
| **iii.** Since your last IRB review, how many subjects discontinued **due to an Adverse Event** (AE), *except death*? | | |  |
| **iv.** Since your last IRB review, how many subjects **withdrew by their choice**? | | |  |
| **v.** Since your last IRB review, how many subjects were **withdrawn by the PI** (i.e., subject non-compliance, disease progression, etc.)? | | |  |
| **vi.** Since your last IRB review, how many subjects **died during their participation period**? | | |  |
| **Detailed description** of the reason for each **subject withdrawal** **since the last IRB review**. | | | |
|  | **N/A** – No subjects have withdrawn from the research since the last IRB Review. **Go to Question 11**. | | |
| *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), describe the screen failure* | | *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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| **11**.Does this study involve **obtaining consent**? (Including studies where documentation of consent was waived) | | | | | |
|  | No. Consent was waived by the IRB for all subjects participating. **Go to Question 14.** | | | | |
|  | Yes. **If yes,** answer the following questions: | | | | |
|  |  | | **Yes** | **No** | **N/A**  No subjects enrolled |
| Was consent obtained for all subjects enrolled **since the last IRB review**? | |  |  |  |
|  | If **No, explain here 🡪** | | | |

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| **12**. Is this study approved for [**surrogate consent**](https://www.uthscsa.edu/vpr/services/glossary#Surrogate-Consent) of adult subjects? | | | | | |
|  | No. **Go to Question 13.** | | | | |
|  | 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 🡪** | | | |
| **For Planned Emergency Research:** Summarize efforts made to contact LAR and family members | | | | | |
|  | N/A | | | | |
| **Describe here 🡪** | | | |

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| **13**. Status of your currently approved consent forms | | |
|  | **Not currently using consent form(s) because** the research is permanently closed to enrollment and no new risks have been identified during this approval period. **Go to Question 14.** | |
|  | **Not using consent form(s) because** the IRB approved a waiver of documentation of consent. **Go to Question 14.** | |
|  | **Currently using** the following IRB approved consent form(s): | |
| **Insert number of approved consent forms currently in use or will be used in the future here** (*these consent forms will be included in the reapproval the IRB at this time)***🡪** |
| **List approved consent form(s) no longer in use** *(e.g. enrollment is complete for Arm A but not complete for Arms B and C – you will no longer use Arm A consent)* **🡪** |

**Summary of Study Progress**

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| NOTE: Provide a summary of the progress you have made since the last IRB review.  DO NOT restate information provided elsewhere – this section is intended to provide the IRB with information on how the study is progressing. |

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| **14**.Summary of**Study Progress and activities** at this site ***since last IRB review.*** |
| Summarize your study’s progress toward achieving the objectives of the study. *NOTE: If you are experiencing problems or delays, explain the situation and your plan for resolving the problems/delays.*  ***If you are following subjects (considered active), provide specific descriptions of the follow-up (phone call only, additional procedures, etc.). When describing procedures, indicate whether they are standard care or research driven.*** |
| **Describe here 🡪** |

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| **15**. **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 16.** | | | | |
|  | **No.**  If **No**, explain the lack of research activity since the last review. *You should describe whether or not your study will still meet its recruitment goal.* *Provide justification for the study remaining open if no activity occurred in the last year.* | | | | |
|  |
| **Explain here 🡪** | | | | |
|  | **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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| **16**. Have there been any departures in study activities from the currently-approved protocol initiated by the investigator, study staff, or study subjects (i.e. procedures/labs done outside the window, missed visits, procedures/labs not conducted, discrepancies in medication inventories)? | | | | | | | | | | | | | | |
|  | | | **No. Go to Question 17** | | | | | | | | | | | |
|  | | | **Yes. Based on your review of all departures since the last review and also for the entire study answer the questions below:** | | | | | | | | | | | |
|  | **(i)** Taking into account all the departures individually and collectively, have **any** of these occurrences had an effect on or possibly affected subject rights, safety or welfare? | | | | | | | |  | | **Yes** | |  | **No** |
|  | **Explain** your answer (**yes *or* no**)**🡪** | | | | | | | | | | | | | |
|  | **(ii)** Taking into account all the departures individually and collectively have **any** of these occurrences had an effect on or possibly affected the science of the study? | | | | | | | |  | | **Yes** | |  | **No** |
|  | **Explain** your answer (**yes *or* no**)**🡪** | | | | | | | | | | | | | |
|  | **(iii)** For **any** occurrences due to failure of **study personnel or support staff** to follow the protocol, summarize the circumstances which lead to the events | | | | | | | | | | | | | |
|  | | | **Provide** details here **🡪** | | | | | | | | | | | |
|  | **(iv)** Do any actions need to be taken (or have they been taken) to prevent reoccurrence? | | | | | | | |  | | **Yes** | |  | **No** |
|  | If **yes**, provide details here**🡪** | | | | | | | | | | | | | |
|  | **(v)** Did you report **any** possible noncompliance in the past year – even if the IRB determined the event was not noncompliance? | | | | | | | |  | | **Yes** | |  | **No** |
|  | If **yes**, list the noncompliance previously reported below: | | | | | | | | | | | | | |
| **Date Reported** | | **Brief description of the noncompliance** | **Did the IRB (or designated reviewer) determine the event to be noncompliance?** | | | | | | | | | |
|  | |  |  | **Yes** |  | **No** | |  | | **N/A –** *under review* | | |

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| **17**. Is this a [**multi-center study**](https://www.uthscsa.edu/vpr/services/glossary#Multicenter-Research) 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 (AE), adverse device effects, 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, adverse device effects, other (non-AE) problems and UPIRSOs since the last IRB review and also for the entire study to answer the following questions. |

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| **18**. Taking into consideration all experiences and safety-related information, have any problems (AE or non-AE) occurred (locally or externally if multi-center) since the last IRB review? | |
|  | **No. Skip to Question 23** |
|  | **Yes. Go to Question 19** |

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| **19**. Have the problems been of the nature and occurred at the frequency and severity that were unanticipated?  (in order to determine frequency, you should consider all AE’s and Non-AE’s that have occurred since the study started) | |
|  | **Yes.** There have been **unanticipated** problems (i.e., events are not listed in protocol or consent form(s); occurred more often or more seriously than expected; or considering the underlying condition of the population, occurred more often or were more serious than expected). **Go to Question 20** |
|  | **No.** Problems have occurred as **anticipated** (i.e., events are listed in protocol or consent form(s), or considering the underlying condition of the population, the events are expected). **Skip to Question 22** |

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| **20**. Were **any** of the unanticipated problems identified in question 19, at least **probably related** to the research? | |
|  | **Yes.** There have been unanticipated problems that are probably or definitely related. **Go to Question 21** |
|  | **No. Skip to Question 22** |

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| **21**. Have the unanticipated and possibly related problems been **serious or do they suggest a greater risk than previously known**? | |
|  | **Yes. Go to Question 22** |
|  | **No. Go to Question 22** |

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| **22**. Did *you report* ***any*** *possible UPIRSOs in the past year – even if the IRB determined the event was not a UPIRSO?* | | | | | | | | | | |
|  | **No.**  If you answered **Yes** to ***ALL*** for 19, 20 **AND** 21, complete A & B below: | | | | | | | | | |
|  | **A** | **Explain** why prompt reporting was not accomplished **🡪** | | | | | | | |
|  | **B** | **AND** Attach a new “Notification of Possible UPIRSO” to this progress report. | | | | | | | |
|  | **N/A** | I did not answer **Yes** to ***ALL*** for questions 19, 20 **AND** 21. | | | | | | | |
|  | **Yes.** List the UPIRSO’s previously reported below. | | | | | | | | | |
| **Date Reported** | | | **Brief description of the UPIRSO** | **Did the IRB (or designated reviewer) determine the event to be a UPIRSO?** | | | | | |
|  | | |  |  | **Yes** |  | **No** |  | **N/A –** *under review* |

**Special Populations**

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| **23**. Is this study approved to recruit any of the following **special populations?** | | | | | |
|  | No. | | | | |
|  | Yes. **If yes,** complete the **Vulnerable Population** table below: | | | | |
| **Vulnerable Population** | | **Yes** | **No** | **Number since** | |
| **last review** | **study start** |
| Children | |  |  |  |  |
| Pregnant women/fetuses | |  |  |  |  |
| Pregnant women for follow-up *(i.e. those enrolled, withdrawn due to pregnancy, and being followed for pregnancy outcomes)* | |  |  |  |  |
| Pregnant Partner *(for Follow-up* ***only****)* | |  |  |  |  |
| Non-viable neonates / neonates of uncertain viability | |  |  |  |  |
| Prisoners | |  |  |  |  |
| Cognitively impaired (adult surrogate consent) | |  |  |  |  |
| Inclusion criteria **targets** economically disadvantaged | |  |  |  |  |
| Inclusion criteria **targets** educationally disadvantaged | |  |  |  |  |

**Other Sources of Relevant Information**

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| **24.** Does this study have a **safety monitoring** entity**?**  *(for example a data safety monitoring board (DSMB) or independent medical monitor; note this does not include regulatory monitors that inspect the site for adherence to the protocol or data collection )* | | |
|  | **No.** | |
|  | **Yes.** If yes: Was a report received since the last IRB review? | |
|  | **No**. |
| **If no,** Indicate a date when a report will be available or provide a reason why a written report is not available 🡪 |
|  | **Yes**. |
| **If yes, summarize here (do not simply refer to attachment)** 🡪 |

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| **25**. If this is a **multi-centered trial**, have there been any other multi-center **reports or notices** relevant to your study since the last review?  *(For example a study sponsor safety alert or black box warnings, annual updates, or other memorandums)* | |
|  | **N/A.** Not a multi-center trial. |
|  | **No.** |
|  | **Yes. *If yes:*** The following is a brief summary of the substantive safety issues contained in the report: |
| **Enter Summary here** 🡪 |

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| **26**. A search of the **recent literature that may be relevant to the research** is *required*. How was the search completed? | |
|  | The study sponsor was contacted for an update on the literature. |
|  | The local PI performed a search of the relevant literature (enter date below) |
|  | **Enter date performed here (must be in the last 6 months)** 🡪 |

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| **27**. *Summarize* the **recent literature that may be relevant to the research.** | |
|  | There has been no new literature published. |
|  | There has been new literature published. |
|  | Provide a **summary** and **implications** for subjects 🡪 |

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| **28**. Is there any **other new information** related to the science, risks or benefits or that alters the risk/benefit ratio of this study? | |
|  | No. |
|  | Yes. |
|  | Provide a **summary** and **implications** for subjects 🡪 |

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| **29. Funding Details** -provide the specific funding source and/or cooperating organization(s):  ***Copy, paste, and complete this table for each funding source*** | | |
|  | **Not applicable (study is not currently funded)** | |
|  | **This study has Federal Funding (**[**examples of Federal funding**](https://www.grants.gov/web/grants/learn-grants/grant-making-agencies.html)**)** | |
|  | **This study has other funding** | |
| **Specific agency or sponsor’s name**: | |  |
| **Grant Title or Contract Title**: | |  |
| **Granting organization or sponsor’s tracking number**: | |  |
| **Is this funding source consistent with information currently on file in the IRB office?**  ***(refer to your most recent approval letter for funding information on file)*** | | |
| |  |  | | --- | --- | |  | **Yes.** | |  | **No.** | | ***If no explain* here** 🡪 | | | | |

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| **30**. **Conflict of Interest** **and Scope of Practice for members of the study staff** | |
| I understand as the Principal Investigator, I am responsible to ensure all members of the study staff declare any potential conflicts of interest or commitment related to this study and work within their assigned duties and approved Research Scope of Practice. Changes to either conflict of interest, assigned duties, or research scope of practice must be reported. **I certify that:** | |
| *Select one:* | |
|  | There have been **no changes** to the status of possible financial conflict of interest for **any of the study staff members**, or their families, with respect to this study. |
|  | There **have been changes** relative to possible financial conflict of interest. I have submitted the required HSC COI Disclosure Form X for review by the COI Committee. [Reminder: for studies conducted at the VA, you must also declare COI using the VA’s [Research Financial COI Statement](http://www.southtexas.va.gov/Research/Documents/LFf.pdf) and submit to the VA R&D Office] |
| *Select one:* | |
|  | There have been **no changes** to the assigned duties and approved Research Scope of Practice for any of the study staff members, with respect to this study. |
|  | There **have been changes** relative to assigned duties and/or approved Research Scope of Practice. I have submitted the required amendment with changes to the Research Institutional Form or Inst-M – Personnel Form or B-2 Personnel Form and updated Research Scope of Practice form. |

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| **31**. **Clinical Trials** |
| Not applicable. *(The study is* ***not*** *registered on UTHSA clinicaltrials.gov.)*  This study is registered on UTHSA clinicaltrials.gov, PI must acknowledge the following:  I understand as the Principal Investigator, I am responsible for maintenance, updating and result reporting on my  Clinical Trial record in [ClinicalTrials.gov](https://register.clinicaltrials.gov/)  I have updated my record to reflect all relevant changes to the protocol  The required annual updates have been made to my study record to reflect study status  I have verified that the contact information for my [ClinicalTrial.gov](https://register.clinicaltrials.gov/) record is correct  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.  I am aware that Consent forms may also be posted on ClinicalTrials.gov where applicable, after recruitment closes,  but no later than 60 days after the last study visit by any subject for federally funded Clinical Trials. |

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| **32**. **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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| **33. List of Institutions Under UTHSCSA IRB Jurisdiction –** *(Check All That Apply)* | | | |
| **Institutions ceding review to the UTHSCSA IRB (IRB of Record)** | | | |
| **Check all that apply** | **Name of Institution / Study Site**  **(list all participating sites below)** | **Choose one** | |
| **Employees of this institution are “engaged” in this research** | **Employees of this institution are not “engaged” in this research”** |
|  | **UTHSCSA** | [Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) | Not engaged;  employees (or [agents](https://www.uthscsa.edu/vpr/services/glossary#Agent)) will not be engaged in research, but this will be a Study Site |
| Including any of the following: School of Medicine, CTRC at UTHSCSA (IDD or SWOG), IIMS **F**IRST **O**utpatient **R**esearch **U**nit (FORU), Dental School, School of Nursing, Graduate School of Biomedical Sciences, School of Allied Health, Research Imaging Center (RIC), College of Pharmacy/UT Austin, UT Medicine, Regional Academic Health Center (**RAHC**)  click here to type Other |
|  | **South Texas Veteran’s Healthcare System (STVHS)** | [VA Research](https://www.uthscsa.edu/vpr/services/glossary#VA-Research) | A separate [VA Continuing Review form](http://www.southtexas.va.gov/SOUTHTEXAS/Research/Documents/ContinuingReviewFormHumanStudies.doc) is required. Submit this form to the VA R&D Office. |
| Including any of the following: Audie Murphy Medical Center, **B**artter **R**esearch **U**nit (BRU) IIMS-FIRST Program, Outpatient Clinics Division, Kerrville |
|  | **University Health System (UHS)** | [Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) | Not engaged;  (Study Site Only). |
| Including any of the following: University Hospital, University Health Center Downtown, University Center for Community Health (UCCH), UCCH/Texas Diabetes Institute (TDI), University Family Health Centers, UHS Breast Imaging Ctr / CTRC, Correctional Health Care Services |
|  | **Christus Santa Rosa Health Care (CSRHC)** | [Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) | Not engaged;  (Study Site Only). |
| Including any of the following: CHART Center (IIMS-FIRST Program) CSRHS, Family Practice Residency, Christus Santa Rosa Hospital |
|  | **Baptist Health System (BHS)** | [Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) | Not engaged;  (Study Site Only). |
| Including any of the following: Baptist Medical Center, Northeastern Baptist Hospital, North Central Baptist Hospital, Southeast Baptist, St. Luke’s Hospital |
|  | **UT Institution**  Collaborative research involving investigators from both UTHSCSA and another UT institution component under the UT System Reciprocity Agreement | [Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) | Not engaged;  (Study Site Only). |
|  | **Texas Biomedical Research Institute (TBRI)** | [Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) | Not engaged;  (Study Site Only). |
|  | **Southwest Research Institute (SwRI)** | [Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) | Not engaged;  (Study Site Only). |
|  | **College of Pharmacy, UT Austin (at UTHSCSA)** | UT College of Pharmacy will be [engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) in research | |
|  | **Other Institution(s)**  [**Covered by UTHSCSA IRB Sharing Agreement**](https://www.uthscsa.edu/vpr/services/glossary#Affiliated-Institution)  **Insert Name(s):** click here to type (names) | [Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) |  |

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| **34**. Which items are being **attached** to this Progress Report? *Check all that apply.* | |
|  | Form A-1, Multipurpose Signature Assurance Sheet - **Required** |
|  | Revised Consent Form(s) with changes to **names and/or contact information and/or new template wording** |
|  | DSMB report or independent medical monitor report |
|  | Sponsor reports or notifications |
|  | New information on risks or benefits |
|  | Notification of Possible UPIRSO form (with separate Form A-1) |
|  | Form X – Conflict of Interest (submit if item 31 above represents a change in COI) |
|  | Report of Possible Noncompliance (with separate Form A-1) |
|  | 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) |