UT Health Science Center San Antonio

**Repository Progress Report**

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| **Request for reapproval of a Local Repository** |

Form Instructions:

* Use this progress report to request re-approval of a local repository. (Do not use this form for local repositories that are combined with an IRB approved research study).

Do not delete any tables on this form. Click here to 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: |  |
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| 1. PI’s e-mail address:
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| 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?** |
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 | **No.** Go to Question 6. |
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 | **Yes.** *If yes,* ***select******one.***  |
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 | All changes implemented have been previously reported to and approved by the IRB. Complete question 5 |
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 | 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 the continuation review of this progress report. 1. The names and contact information provided in previously approved consent form(s)
2. Addition of new wording from the current HSC consent template to consents based on older versions of the consent template. *(a separate amendment is not required)*
3. Indicate this as a multi-center study that the sponsor has authorized competitive local enrolment.

**[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)* |
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 | **No.** Go to Question 7. |
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 | **Yes.** Note: You may only choose from the options listed below. **Check all that apply.** |
| **Minor Modifications Request** *(Amendment Form Not Required)* |
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 | **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?  |

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 | **Yes -** attached a revised consent form (track changes) |

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 | **No** |
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 | **Update name(s) and/or contact information in a consent form**. *Attach a revised consent form (track changes)*Summarize changes here **🡪**:  |
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 | **Update a consent form with new IRB approved wording from the latest consent template**. *Attach a revised consent form (track changes)*Summarize changes here **🡪**:  |

**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**. **Repository Collection Activities** - Select the statement(s) that apply to the **materials being collected for the repository** (m*ore than one may be selected)* and provide the **status of the applicable collection activities**  |
| **Check**  | **Collection Categories** | **Current Status**(Choose one statement for each category)  |
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 | Consent for banking was waived **AND**using existing clinical materials Existing materials that were collected solely for non-research purposes (such as medical treatment or diagnosis) **AND** consent was not obtained to store these materials for future research studies.  |

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 | Collection of existing clinical materials continues or is planned for the future.(Existing when approved by IRB) |
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 | Collection of existing clinical materials is complete; all materials have been transferred to the repository. |
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 | Consent for banking was obtained **AND**using existing or leftover clinical materialsMaterials that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) for which consent and authorization for future use (banking) was/will be obtained by researchers collecting data/specimens for the repository.  |

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 | Collection of clinical materials and consent continues or is planned for the future. |
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 | Collection of clinical materials is complete; all materials have been transferred to the repository. |
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 | Consent for banking was obtained **AND**using existing or leftover research materialsMaterials that have been or will be collected for research purposes under another IRB approved research and consent and authorization for future use was/will be obtained by researchers collecting data/specimens for the repository. |

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 | Collection of research materials and consent continues or is planned for the future. |
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 | Collection of research materials is complete; all materials have been transferred to the repository. |
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 | Consent for banking was obtained **AND**using materials obtained solely for use in the repositoryMaterials that will be collected specifically for inclusion in the repository (under this repository approved protocol) for which consent and authorization for future use will be obtained by researchers collecting data/specimens for the repository.  |

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 | Collection of repository materials and consent continues or is planned for the future. |
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 | Collection of repository materials is complete; all materials have been transferred to the repository. |

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| **8A**. **Number of subjects** (or records/specimens) **accrued.** *[From all study sites in which this IRB approval covers]*Note for repositories only accruing existing data/specimens (not interacting with subjects) – for this section, obtaining an individual’s information or specimens is considered enrolling subjects. Please include these numbers in the table below. |
| **Local***(at all sites in which this irb approval covers )* | **Total Number** |
| **i.** How many subjects’ data/specimens have been included in the repository **since last IRB review?** |  |
| **ii.** How many subjects’ data/specimens have been included in the repository **since the repository was started?** *[If this is the first progress report, this number should be the same as B, above. If not the first report, this number should equal the total from your last report plus B above]* |  |
| **iii.** How many subjects have completed the repository collection phase? |  |

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| **8B**. **Number of Veteran subjects** (or records/specimens) **accrued.**  |
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 | Check here if study does not involve South Texas Veteran’s Healthcare System (STVHS)**Skip to Question 8C.** | **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? |  |
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 | **Yes If Yes, Complete Question 8.iii.**  |

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 | **No If No, Skip to Question 8C.** |  |
| **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? |  |
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 | **Yes**  |

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 | **No**  |  |

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| **8C. 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.**  |
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 | Check here if study does not involve other study sites**Skip to Question 8D.** | **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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| **8D. Major Categories of Withdrawals** *(since the last IRB review) [From all sites in which this IRB approval covers]* |
|  | Check here if repository only involves accruing data/specimens (does not involve interacting with subjects). Skip to Question **13**. | **Total Number** |
| **D.** During the collection phase, how many subjects were Screen failures *(i.e., signed consent & completed only part or all of screening)?* |  |
| **E.** During the collection phase, how many subjects discontinued due to an Adverse Event (AE), *except death*? |  |
| **F.** During the collection phase, how many subjects were withdrawn by PI (i.e., subject non-compliance, disease progression, etc.)? |  |
| **G.** During the collection phase, how many subjects died during their participation period? |  |
| **H.** How many subjects withdrew by their choice? |  |
| **Total Withdrawals** |  |
| **I. Total number of withdrawals since the study started** |  |

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| **9**. **Detailed description** of the reason for **subject withdrawal** noted above since the last IRB review. |
|  | **N/A** – No subjects have withdrawn from the repository 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), describe 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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| **10**.Does this study involve **obtaining consent**? (Including studies where documentation of consent was waived) |
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 | No. Consent was waived by the IRB for all subjects participating. **Go to Question 13.** |
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 | 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**? |

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|  | If **No, explain here 🡪**  |

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| **11**. Is this repository 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 repository since the last IRB review? |  |  |
| How many subjects who were enrolled by surrogate consent have subsequently **decided not to continue** in the repository since the last IRB review? |  |  |
| Describe the reasons why subjects enrolled by surrogate consent later **did not agree to continue in the repository**. |
| **Describe here 🡪**  |

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| **12**. Status of your currently approved consent forms |
|  | **Not currently using consent form(s) because** the repository is permanently closed to enrollment and no new risks have been identified during this approval period. Go to Question 13. |
|  | **Not using consent form(s) because** the IRB approved a waiver of documentation of consent.Go to Question 13. |
|  | **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 Repository Operation**

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| NOTE: Provide a summary of the operation of the repository 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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| **13**.Summary of**repository operations and activities** at this site ***since last IRB review.***  |
| Summarize your experience with each of the three repository operations: **collection, storage** and **distribution** of materials for future use. *NOTE: If you are experiencing problems or delays, explain the situation and your plan for resolving the problems/delays.*  |
| **Describe here 🡪**  |

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| **14**. **Subjects' response** to the collection activities since the last IRB review. Please describe how subjects have responded to and tolerated their participation. ***Your******Answers should be substantive.*** |
| Were any subjects actively participating in the collection phase during the period of time since the last IRB review?*Choose one* |
|  | **N/A** – Repository only involves accruing existing data/specimens (does not involve interacting with subjects). Go to Question 16. |
|  | **No.**  If **No**, explain the lack of activity since the last review.  |
| **Explain here 🡪**  |
|  | **Yes.** If **Yes**, answer the following questions: |
| **(a)** How have the repository activities under this IRB approval **affected** the subjects since the last IRB review?  |
| **Explain here 🡪**  |
| **(b)** Have subjects had any **comments or complaints** about their participation in any of the repository activities since the last IRB review? |  | **Yes** |  | **No** |
| If **yes**, provide details here**🡪**  |

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| **15**. Were all **repository procedures/activities** conducted as described in the protocol in the last year? |
|  | **Yes.** |
|  | **No.**  |
| If **No**, **explain here 🡪**  |
|  | **Not applicable – no study activity occurred in the last year.**  |

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| **16**. Is this a **multi-center repository** where collection activities occur at other institutions outside the jurisdiction of the UTHSCSA IRB? |
|  | **No.**  |
|  | **Yes.** Have there been any oversight problems at the satellite collection 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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| **17**. 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 22** |
|  | **Yes. Go to Question 18** |

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| **18**. 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 19** |
|  | **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 21** |

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| **19**. Were **any** of the unanticipated problems identified in question 18, at least **probably related** to the research? |
|  | **Yes.** There have been unanticipated problems that are probably or definitely related. **Go to Question 20** |
|  | **No. Skip to Question 21** |

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| **20**. Have the unanticipated and possibly related problems been **serious or do they suggest a greater risk than previously known**? |
|  | **Yes. Go to Question 21** |
|  | **No. Go to Question 21** |

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| **21**. 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 18, 19 **AND** 20 complete A & B below (otherwise mark N/A): |
|  | **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*** of questions 18, 19 **AND** 20. |
|  | **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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| **22**. Is this repository 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 |  |  |  |  |
| Non-viable neonates / neonates of uncertain viability |  |  |  |  |
| Prisoners |  |  |  |  |
| Cognitively impaired (adult surrogate consent) |  |  |  |  |
| Inclusion criteria **targets** economically disadvantaged |  |  |  |  |
| Inclusion criteria **targets** educationally disadvantaged |  |  |  |  |

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| **23**. **Details of Repository Distribution Activity** |
|  | N/A – Not distributing any materials collected for this repository |
|  | N/A – Materials have not yet been distributed to researchers, but distribution may occur in the future. |
|  | Yes- Materials collected for this repository were distributed. (List where the materials were distributed below) |
| **Details on Repository Activity** (for each distribution, include whether **identifiable** or **de-identified** materials were provided) | **Recipient Study Information**  |
| List other research studies (including IRB study #) given data and/or specimens from your repository **since the last review here 🡪** |  |

**Other Sources of Relevant Information**

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| **24. 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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| **25**. *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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| **26**. 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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| **27. Funding Details** -provide the specific funding source and/or cooperating organization(s):  ***Copy, paste, and complete this table for each funding source*** |
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 | **Not applicable (study is not currently funded)** |
| **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)*** |
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|  | **Yes.**  |
|  | **No.**  |
| ***If no explain* here** 🡪 |

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| **28.** **Conflict of Interest** – *Only Select One*  |
| 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 that they report these to the Conflict of Interest Committee. **I certify that:** |
|  | 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](https://www.uthscsa.edu/sites/default/files/Services/forms/form_x.docx) 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 change to the Institutional Form, or Inst-M – Personnel Form or Form B-2 Personnel Form and updated [Research Scope of Practice Form](https://www.uthscsa.edu/sites/default/files/Services/forms/scopeofpractice.pdf).  |

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| **29. List of Institutions Under UTHSCSA IRB Jurisdiction –** *(Check All That Apply)* |
| **Institutions Affiliated with the UTHSCSA IRB (IRB of Record) “**[**UTHSCSA IRB Affiliated Institutions**](https://www.uthscsa.edu/vpr/services/glossary#Affiliated-Institution)**”** |
| **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”** |
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 | **UTHSCSA**  |

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[Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) |

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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 |
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 | **South Texas Veteran’s Healthcare System (STVHS)** |

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[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 |
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 | **University Health System (UHS)** |

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[Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) |

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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 |
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 | **Christus Santa Rosa Health Care (CSRHC)** |

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[Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) |

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Not engaged;(Study Site Only). |
| Including any of the following: CHART Center (IIMS-FIRST Program) CSRHS, Family Practice Residency, Christus Santa Rosa Hospital |
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 | **Baptist Health System (BHS)** |

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[Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) |

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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 |
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 | **UT Institution**  Collaborative research involving investigators from both UTHSCSA and another UT institution component under the UT System Reciprocity Agreement |

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[Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) |

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Not engaged;(Study Site Only). |
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 | **Texas Biomedical Research Institute (TBRI)** |

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[Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) |

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 | **Southwest Research Institute (SwRI)** |

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[Engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) |

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Not engaged;(Study Site Only). |
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 | **College of Pharmacy, UT Austin (at UTHSCSA)** |

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UT College of Pharmacy will be [engaged](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research) in research |
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 | **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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| **30**. Which items are being attached to this Progress Report? *Check all that apply.* |
| X | Form A-1, Multipurpose Signature Assurance Sheet (or email from PI) - **Required** |
|  | Revised Consent Form(s) with changes to **names and/or contact information and/or new template wording** |
|  | New information on risk or benefits |
|  | Notification of Possible UPIRSO form (with separate Form A-1) |
|  | Form X – Conflict of Interest (submit if item 28 above represents a change in COI) |
|  | Report of Noncompliance (with separate Form A-1) |
|  | Publication(s) or meeting proceedings |
|  | Other: (describe) |