UT Health San Antonio (UTHSA)

**Institutional Project Update Form**

**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

|  |  |
| --- | --- |
| **3. Summary.** Provide a descriptive update/summary of progress made on this project. Any problems/delays (e.g. recruitment difficulties) should be included. | |
|  |

|  |  |  |
| --- | --- | --- |
| **4. Reporting Requirements** Did any of the following events occur during the previous reporting period?  *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. | |
| No | Provide details: | |

|  |  |
| --- | --- |
| **5. 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:** | |
| ***Conflict of Interest****, 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](https://www.uthscsa.edu/sites/default/files/Services/forms/form_x.docx) or through [iDisclose](https://vpr.uthscsa.edu/iDisclose/) 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 and submit to the VA R&D Office] |
| ***Scope of Practice****, Select one:* | |
|  | **Not applicable**, not interacting or intervening with living individuals for research purposes. |
|  | 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 changes to the roles section on the Institutional Research Application or [Inst-M – Personnel Form](https://www.uthscsa.edu/sites/default/files/Services/forms/form_inst_m.docx) or B-2 Personnel Form and updated the [Research Scope of Practice form](https://www.uthscsa.edu/sites/default/files/Services/forms/scopeofpractice.pdf). |

|  |  |  |
| --- | --- | --- |
| **6. 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. |

|  |  |  |
| --- | --- | --- |
| 7. **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.* |

|  |  |
| --- | --- |
| **8.** **External IRB Studies** | |
| Not applicable. (UTHSA is the IRB of Record for this study) | |
| External IRB Name: |  |
| External IRB Number: |  |
| Status: | IRB expiration date:  Current IRB continuing review letter is attached  N/A, IRB continuing review not required  Informed consent document *(select one)*:  Current version has been reviewed and approved by OCR for institutional requirements.  Current version has **not** been reviewed and approved by OCR for institutional requirements. A copy if **attached** for review.  Not applicable, consent was waived or not required |