UT Health San Antonio (UTHSA)

Institutional Treatment Application

| UTHSA Tracking Number |
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| **Item 1** Title | Not applicable, already provided on Form tB |
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| **Item 2** Principal Investigator | Not applicable, already provided on Form tB | | |
| First Name\* |  | Last Name\* |  |
| Organization\* |  | Department\* |  |
| Degree(s) |  | Cell Phone or Pager |  |
| Preferred email |  | Office Phone\* |  |
| PI’s Point of Contact |
| First Name\* |  | Last Name\* |  |
| Office Phone\* |  | Cell Phone or Pager |  |
| Preferred email \* |  | | |
|  |  | | |

\*\*Required fields

| **Item 3** Select the IRB you wish to use.  *Select one*  \*\* if you select an external IRB, not all study sites are permitted. Further details are available on the OCR website: <https://www.uthscsa.edu/vpr/services/cooperative-research-single-irb-external-irb> | UTHSA IRB  Another UT System IRB  NCI IRB  GPC IRB  National Dental PBRN Central IRB  Western IRB (WIRB)  SMART IRB (specify):  Other External IRB (specify): |
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| **Item 4** Where will the drugs, biologics, or devices be stored and managed?  *(check all that apply)* |

|  |  |
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| Hospital Pharmacy | If checked, list hospital(s): |
| Commercial Pharmacy | If checked, list pharmacy: |
| Investigational Drug Section of CTRC |  |
| Other location(s) approved by  the Office of Clinical Research (OCR) | If yes, provide OCR site approval number(s): |
| Other location(s) **NOT** approved by  the Office of Clinical Research (OCR) | If yes, attach approval request [*OCR Policy for Drug/Device Storage*](https://www.uthscsa.edu/sites/default/files/Services/forms/ocr1.1.2-control-inv-article.pdf) |
| Are you transferring the drug(s)/device(s) between institutions? | No  Yes, *attach letter or memorandum of understanding for originating institution and each receiving institution* [*Pharmacy LOU*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_inst_g.docx) |

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| **Item 5** Sharing of Data/Specimens to Entities Outside the Affiliated Study Sites | | | | | | | | | |
|  | | Not applicable, not sharing data/specimens with groups outside of the Affiliated study sites | | | | | | | |
| **Entity**  *(select all applicable)* | | | For each entity, **select all applicable** | | | | | | |
| **Identifiable materials** | | [**Limited Data Set**](http://privacyruleandresearch.nih.gov/dictionary.asp#l) **(i.e. may include elements of dates, city, state, zip)** | | **Non-identifiable materials** | | *If information will leave the covered entity:*  **Describe how the materials will be transferred from one location to another.**  *If using eCRF, provide website.*  *Note – those entities receiving identifiable information or a limited data set must also be listed on the HIPAA authorization.* |
| **Viewed** | **Transferred** | **Viewed** | **Transferred** | **Viewed** | **Transferred** |
|  | Sponsor and/or CRO | |  |  |  |  |  |  | Describe:  or N/A data will not leave the covered entity |

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| **Item 6** Treatment Activities - Identify, consent or enroll patients. N/A | | |
| **UTHSA**  *Mays Cancer Center*  *MARC* *Specify Clinic*:  *Dental School* *Specify Clinic*:  *Oral & Maxillofacial Surgery/Implant Clinic*  *Other Department* *Specify*: | **University Health System (UHS)**  *University Hospital* *Specify Department or location*:  *Robert B. Green (RBG)* *Specify Clinic*:  *Texas Diabetes Unit (TDI) Specify Clinic*:  *Other Department or Clinic*: | **Other Institution(s)** *Specify*:  Department |