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       |