UT Health San Antonio (UT Health SA)

Institutional Research Application

***DO NOT SUBMIT THIS FORM FOR A CLINICAL TRIAL UNLESS YOU HAVE BEEN INSTRUCTED TO DO SO BY THE CTO OFFICE.***

*This form is for* ***non-clinical trials*** *only.*

*Items marked with the* IRB review *icon indicate fields that the institution and the UT Health SA IRB share. These fields will not be shared with external IRBs.*

Using this form – To check the checkboxes, click once on the box. To enter text, click once on the gray box and then type your response.

| UT Health SA Tracking Number | |
| --- | --- |
| IRB review **Item 1** Title |  |

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| **Item 1a** Is this an exempt or chart review study? |  | No |
|  | Yes |

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| IRB review **Item 2** Principal Investigator | | | |
| First Name\* |  | Last Name\* |  |
| Organization\* |  | Department\* |  |
| Degree(s)\* |  | Job Title |  |
| Preferred email\* |  | Office or Cell Phone |  |
| PI’s Point of Contact |
| First Name\* |  | Last Name\* |  |
| Preferred email\* |  | Office or Cell Phone |  |

\*Required field

| IRB review **Item 2b** 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> |  | UT Health SA IRB |
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|  | NCI IRB |
|  | SMART IRB (specify): |
|  | Other External IRB (specify): |

| **Item 3** Does the research fall under the purview of any other departments, committees, or agencies? | Yes | No |
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| Principal Investigator’s Department Chair or equivalent | Attach signed [Form A](https://www.uthscsa.edu/sites/default/files/Services/forms/form_a.pdf) | |
| IRB review Radiation Safety Committee *(submit* [*Form Q*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_q.doc) *as part of RSC application)*  *(radiation exposure, radioactive materials, radiation generating equipment)* | Pending  Approval notice attached |  |
| IRB review Radioactive Drug Research Committee *(submit* [*Form Q*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_q.doc) *as part of RDSC application)*  *(radioactive material not covered by IND)* | Pending  Approval notice attached |  |
| IRB review Institutional Biosafety Committee *(submit* [*Form Q-1*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_q-1.docx) *as part of IBC application)*  *(biologic hazards, microbiologic or viral agents, pathogens, cell lines, vaccine trials, recombinant DNA, human gene therapy)* | Pending  Approval notice attached |  |
| Mays Cancer Center (MCC) Protocol Review Committee (PRC)  *(all cancer related research regardless of funding)* | Pending  Approval notice attached |  |
| Use of Investigational Stem Cell Treatment |  |  |
| Texas Dept. of Family and Protective Services [Request for Approval](https://www.uthscsa.edu/sites/default/files/Services/forms/form_inst_j.pdf)  *(research involving Child Protective Services)* | Pending  Approval notice attached |  |
| VA Research and Development Committee  *(required of all studies being conducted at the VA)* | Submit [Protocol Application](https://www.southtexas.va.gov/research/protocol.asp) to VA R&D Office |  |
| IRB review Patient Data Governance Committee | [DAUR](https://www.uthscsa.edu/sites/default/files/Services/forms/daur-request.docx) Form attached |  |
| IRB review General Data Protection Regulation (GDPR) *(required when studies are targeting research subjects in the European Union and European Economic Area ) –* [*GDPR Guidance*](https://www.uthscsa.edu/sites/default/files/Services/forms/gdpr_guidance.pdf) | Required consent form language has been included |  |
| IRB review [NIH Genomic Data Sharing Policy](https://grants.nih.gov/grants/guide/notice-files/not-od-14-124.html) *(required for the sharing of human genomic and phenotypic data generated in NIH-funded research)* | [Extramural Institutional Certification](https://osp.od.nih.gov/wp-content/uploads/GDS_Extramural_Certification.pdf) Attached |  |
| * [NIH Data Management and Sharing Policy](https://library.uthscsa.edu/nih-data-management-and-sharing-plan/) | DMS Plan attached |  |
| IRB review [NIH Certificates of Confidentiality](https://grants.nih.gov/policy/humansubjects/coc/helpful-resources/suggested-consent.htm) (*required For NIH or VA funded research and where a Certificate of Confidentiality is issued)* | Required consent form language has been included |  |
| * [U.S. Department of Education (Family Educational Rights and Privacy Act (FERPA)](https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html) | Pending  Approval notice attached |  |
| Other: | Pending  Approval notice attached |  |

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| IRB review **Item 4** Are there multiple sites **under the direction** of the local PI or for which the UT Health SA IRB will be the reviewing IRB?  ***Note: You may select both “Yes” statements if study will include local affiliate and non-affiliated study sites.*** |  | No, not a multi-site study under direction of local PI. | |
|  | Yes, limited to UT Health SA, University Health or VA | *VA Studies Only*  PI (if different from study PI):  Co-PI (if applicable):  N/A – same PI |
|  | Yes, non-affiliated sites are included (other than UT Health SA, VA, or University Health).  Submit a Communication Plan for non-affiliated sites under the direction of the local PI.[Example](https://www.uthscsa.edu/sites/default/files/Services/forms/communicationplan.docx) Communication Plan for Investigator Initiated Study | |

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| IRB review**Item 4a**UT Health SA or total for all local affiliate sites | | |
|  | N/A, Does not include UT Health SA, University Health, or VA. | |
| Number of subjects (or records, samples, images, etc.) to be screened for eligibility:  *Note: This number should include all subjects who will be considered for the study prior to screening and/or consent.* | |  |
| Target enrollment number for completers:  *Note: This is the number of subjects needed to complete the study in order to answer the research question or reach the desired statistical significance.* | |  |

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| *IRB review***Item 4b** Non-affiliated Study Sites | | | | | |
|  | N/A, UT Health SA, University Health or VA are the only study site(s) | | | | |
| Name of Study Site  *To add rows, use copy & paste* | | Organization’s  Point of Contact (name) & contact information | Is this study site under the direction of the PI? | Does this organization want the UT Health SA IRB to review for them? | |
| No | Yes |
|  | | Same as PI’s point of contact (see page 1) | No  Yes | *Indicate the status of this organization’s IRB approval (or equivalent evidence of institutional support).* | 1. Provide Number of subjects to be screened for eligibility: 2. Provide target enrollment number for completers: |

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| **Item 5** Training for non-study personnel | | |
| **Describe the plan** for training personnel who are not part of the research team and will be administering the intervention(s).  **OR**  **Describe the plan** for training/informing clinical personnel about the study. |  | Not applicable – no training for non-study personnel required |
| Who will you train?  Nurses who will administer the study drugs  Pharmacy staff on receipt, storage, and dispensing primary study intervention  Radiology staff who will administer primary study intervention (radiation treatment)  Other:  *Example: University Health clinical areas impacted by enrollment of subjects and collection of research blood samples. Clinical personnel will receive in-service about study. Nurses will be asked to assist with blood collection.* | |
| When will you provide the training?  Prior to the first subject being enrolled  Each time a new subject is enrolled  Other: | |
| How will you provide the training?  In person  Using paper or electronic documents read by the trainees  Other: | |

| **Item 6**  Recruitment through UT Health SA [Find a Study website](http://vpr.uthscsa.edu/findastudy/) with contact information for prospective subjects’ use? |  | This study requires recruitment assistance.  Assistance updating study record is requested,[Form L-1](https://www.uthscsa.edu/sites/default/files/Services/forms/form_l-1.docx) attached  Study team will login directly and update[Find a Study Website](http://vpr.uthscsa.edu/findastudy) |
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|  | The study does not require recruitment assistance. Do not list on[Find a Study Website](http://vpr.uthscsa.edu/findastudy). |

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| **Item 7** Recruitment Activities - Identify, recruit, consent, or enroll subjects either prospectively or retrospectively.  N/A | | | |
| **UT Health SA**  *Medical records*  *Mays Cancer Center*  *MARC* *Specify Clinic*:  *FIRST Outpatient Research Unit (FORU)*  *Dental School* *Specify Clinic*:  *Oral & Maxillofacial Surgery/Implant Clinic*  *Core Lab or Research Imaging Institute*  *Other Department* *Specify*: | **University Health**  *Medical records*  *University Health* *Specify Department or location*:  *Robert B. Green (RBG)* *Specify Clinic*:  *Texas Diabetes Unit (TDI) Specify Clinic*:  *MARC Heart Station Number of visits*:  *Other Department or Clinic*: | **South Texas Veterans Health Care System (STVHCS)**  *Medical records*  *Audie Murphy Medical Center**Specify Department or location*:  *Barter Research Unit (BRU) IIMS-FIRST*  *FTOPC Specify Clinic*:  *Other Department or Clinic*: | **Other Institution(s)** *Specify*:  *Medical records*  Department |

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| IRB review **Item 8**  Will you be using **private information** during this study? | | *For each column (representing ways that identifiers are encountered or used in research), select either:*   * *None of the identifiers will be used in the activity described by checking “None”, or* * *One or more of those listed will be used in the activity described by checking all applicable identifiers* | | | | |
|  | No - Only using publicly available information | | | | | |
|  | Yes *If yes, check all that are applicable and complete table*  protected health information (PHI) held by a covered entity  other types of private information (i.e., student records); Describe:  research information (non-PHI) that is not publicly available  Clinical Informatics Research Division (CIRD) Data Warehouse in conjunction with other data sources  CIRD is the **only** source of private information  *All data is available from CIRD; no need to access medical records)* | | | | | |
| **List of identifiers/sensitive data**  *Important Note:*  *Complete this table by starting with Column A and moving to the right* | | **Column A**  Looked at by research team | **Column B**  Recorded on an enrollment log, subject list, or key list | **Column C**  Recorded on data collection tools (CRFs, surveys, spreadsheets, etc.) | **Column D**    Recorded on specimen containers | **Column E**  Stored after study completed |
| **Identifiers** | |  |  |  |  |  |
| **None** of the identifiers listed below ↓ | | *If selected –* ***stop***  *Skip to Item 13* |  |  |  |  |
| Names | |  |  |  |  |  |
| a study code that is linked to the individual’s identity using a key that is only accessible by the researcher | | N/A |  |  |  |  |
| Address | |  |  |  |  |  |
| Dates (except year)  *Full or partial dates: date of birth, date of service, date of collection, etc.* | |  |  |  |  |  |
| Ages over 89 | |  |  |  |  |  |
| Phone or Fax numbers | |  |  |  |  |  |
| E-mail addresses | |  |  |  |  |  |
| - Social security numbers,  - Scrambled SSNs (SCRSSNs), or  - the last four digits of a SSN | | Specify: | Specify: | Specify: | Specify: | Specify: |
| Numbers (including)  - Medical record numbers  - Account numbers  - Certificate/license numbers  - Health plan beneficiary numbers  - Vehicle identifiers and serial numbers, or license plate numbers  - Device identifiers and serial numbers | | Specify: | Specify: | Specify: | Specify: | Specify: |
| \*Web Universal Resource Locators (URLs) or Internet Protocol (IP) address numbers | |  |  |  |  |  |
| - \*Biometric Identifiers, including finger and voice prints  - \*Full face photographic images and any comparable images | | Specify: | Specify: | Specify: | Specify: | Specify: |
| Any other pre-existing unique identifying number, characteristic, or code  *e.g., patient initials, image ID number, pathology specimen ID number, etc.* | |  |  |  |  |  |
| Substance use disorder data | |  |  |  |  |  |
| Other sensitive data:  *e.g., HIV status, genetic data, etc.* | |  |  |  |  |  |

\*A Texas state agency may not acquire, retain, and disseminate this information without the individual’s written or electronic consent.

NOTE: Storing this information in a repository may require additional compliance review.

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| IRB review**Item 9** Coding Plan | | *Note: The code, algorithm, or pseudonym should not be derived from other related information about the individual, and the means of re-identification should only be known by authorized parties and not disclosed to anyone without the authority to re-identify records.* |
|  | Not applicable, no identifiable information will be collected | |
| Describe the method that will be used to create and assign a unique study code to the data | |  |
| Describe the method that will be used to create and assign a unique study code to the specimens | | Describe:  **-OR-**  N/A, not collecting specimens |
| What is the format of the key? | | Paper  Electronic  REDCap |
| Who will have access to the key? | |  |
| Where will the key be stored and how will it be protected? *If a key will be located at more than one location, list all applicable. If confidentiality measures differ at the locations, describe differences.* | | Location(s):  Describe confidentiality measures: |

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| IRB review **Item 10** Data / Specimen Storage Plan | | |
|  | Not applicable, coded or identifiable information will not be collected | |
|  | Not applicable, see attached DAUR form | |
|  | Not applicable, see attached NIH DMS Plan | |
| *Check all that apply and complete the table as applicable.*  *If data/specimens will be stored at more than one location, list all applicable. If storage differs at the locations, describe differences.* | | **How will coded or identifiable data/specimens be stored?** |
|  | Paper data *(including completed consent forms)* |  |
|  | Electronic data  *(Consider the computing environment for all research data/images, e.g., platform, number of computers, type of computers, network or standalone computers, access to and security of physical environment, audit capabilities to track access activity,* *closed or open source informatics platforms)* | *Note:*  *If stored on VA server provide the path (e.g., 11vhastxmu15\VA Research\\_\_\_)* |
|  | REDCap  *Refer to* [*REDCap User agreement*](http://deb.uthscsa.edu/files/REDCap_End_User_Agreement.pdf) *for requirements on data storage and access* |  |
|  | Social Security Numbers (SSNs, Scrambled SSNs, or last four digits of an SSN) |  |
|  | Specimens |  |
|  | Long-term storage (following completion of the study and inactivation of IRB approval) |  |
|  | Social media recruitment and screening data |  |
|  | Substance use disorder data | After receiving the data, I confirm that the key, that is linked to the identifiable data, will be destroyed to render the identifying information non-retrievable consistent with *42 CFR Part 2 Confidentiality of Substance Use Disorder Patient Records* |

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| IRB review **Item 11** Calculating HIPAA Disclosures  *Use this table to figure out whether the information being collected and stored will result in a disclosure of PHI. Health information collected by or stored at UT Health SA (even if collected from a non-Covered Entity) should be considered as a possible HIPAA disclosure.* |

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| --- | --- |
|  | Not applicable, not collecting protected health information (PHI) held by a covered entity |

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| **Covered Entity where the source PHI is held** (Source Location) | | | **Research Storage Location(s)** |
| *NOTE:*  *You may list more than one site on a row if the file type* ***and*** *storage locations are exactly the same.* | **Paper files** | **Electronic files** | Where do you plan to store the PHI from this organization? *(list all storage locations – i.e., UT Health SA, University Health, VA, etc.)* |
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| *NOTE: If the* ***Storage*** *location is different than the* ***Source*** *location it is considered a* ***disclosure****.*  *All disclosures must be justifiable and must be listed in the IRB approved HIPAA authorization form or waiver form.* | | | |

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| IRB review **Item 12** What type of HIPAA authorization waiver, if any, are you requesting from an **External IRB?** | | *Note: Most external IRBs will provide HIPAA waivers with IRB approval. This includes commercial (e.g., Advarra, WIRB), academic center, and hospital IRBs.* |
|  | Not applicable, not collecting protected health information (PHI) held by a covered entity | |
|  | Not applicable, using UT Health SA IRB | |
|  | Full waiver of HIPAA authorization *(e.g. chart review)* | |
|  | Partial waiver of HIPAA authorization for access to records for subject recruitment or screening that is not considered activities preparatory to research | |
|  | HIPAA Alteration – altering the required elements of HIPAA Authorization, including omissions of the required elements (e.g. verbal permission with waiver of signature) *\*HIPAA Alteration not allowed at the VA* | |
|  | None, activities are preparatory to research:   * the individual accessing the data is part of the covered entity; and * the data will not be printed, downloaded, copied, saved, data-scraped, or faxed, or any other means by which an individual outside the covered entity might control or retain the data | |
|  | None, the external IRB will not provide a HIPAA Waiver/Alteration of Authorization, a Form J is included for local approval – example: NCI CIRB | |
|  | None, asigned HIPAA authorization will be obtained prior to accessing PHI | |

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| IRB review **Item 13** Maintaining Confidentiality | | |
|  | | Not applicable, no identifiable information will be viewed (looked at) |
| Describe measures that the research team will take to protect the confidentiality of subjects while **looking** at private information (i.e., while viewing medical records) | | |
|  | The researchers will follow all institutional rules and regulations (to include HIPAA or FERPA if applicable) during the time which the data is being accessed. All policies and procedures of the institution (i.e., covered entity) regarding confidentiality of patient data will be followed. | |
|  | **-OR-**  Describe different approach: | |

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| IRB review **Item 14** Sharing of Research Data/Specimens to Entities Outside the Affiliated Study Sites | | | | | | | | | | |
|  | | | Not applicable, not sharing data/specimens with groups outside of the Affiliated study sites | | | | | | | |
|  | | | Not applicable, see attached DAUR form | | | | | | | |
|  | | Not applicable, see attached Data DMS Plan | | | | | | | | |
| *Mark all entities that may have access to subject info linked to research data or specimens* ***either viewed on site or transferred.*** | | | | | | | | | | |
| **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.* * *If using REDCap, indicate if others will be able to download data directly from REDCap.* * *Levels of permissions should be set up correctly and monitored on a regular basis for changes.* * *Note – those entities receiving identifiable information or a limited data set must also be listed on the HIPAA authorization or waiver.* |
| **Viewed** | **Transferred** | **Viewed** | **Transferred** | **Viewed** | **Transferred** |
|  | Sponsor and/or CRO | | |  |  |  |  |  |  | Describe method for viewing:  and/or  Describe method for transferring: |
|  | Monitor | | |  |  |  |  |  |  | Describe method for viewing:  and/or  Describe method for transferring: |
|  | Coordinating Center | | |  |  |  |  |  |  | Describe method for viewing:  and/or  Describe method for transferring: |
|  | Other sites, investigators or collaborators participating in this study. Specify: | | |  |  |  |  |  |  | Describe method for viewing:  and/or  Describe method for transferring: |
|  | Others not participating in this study.  Specify: | | |  |  |  |  |  |  | Describe method for viewing:  and/or  Describe method for transferring: |

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| **Item 15**  Does the study employ the use of electronic study tools to collect, store, and/or share identifiable data such as online platforms (e.g., XNAT), mobile applications (e.g., electronic diaries), or electronic informed consent (e.g., MyTrus)?  *There may be circumstances when a mobile app meets the definition of a mobile medical app and may be subject to FDA regulations. Refer to FDA guidance* [*here*](http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pd) | | | | | | |
| No  Yes, select study tools that will be used *(check all that apply)*: | | | | | |  |
| UT Health SA Complion: e-Regulatory & Source Documentation for remote monitoring (listed in HIPAA authorization) | | | | | | Form NN not required |
| UT Health SA REDCap | | | | | | Complete this section, but do not submit Form NN for **External IRB studies** |
|  | | Data collection | | Obtaining informed consent *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)\** | Mobile App *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)* |
| UT Health SA secure server-based system, specify: | | | | | |
|  | | Data collection | | Obtaining informed consent *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)\** | Mobile App *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)* |
| Commercial sponsor study tools, specify:  Confirm understanding that the sponsor study tools are [FDA 21 CFR Part 11](https://www.fda.gov/media/75414/download) compliant and the company providing the study tools to the sponsor has been named as a disclosure in the HIPAA authorization | | | | | |
|  | | Data collection | | Obtaining informed consent *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)\** | Mobile App *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)* |
| Non-UT Health SA based study tool *(including REDCap maintained at other institutions)* | | | | | | |
|  | | Data collection *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)* | | Obtaining informed consent *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)\** | Mobile App *(complete* [*Form NN*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_nn.docx)*)* | |
|  | | *Required* Include the specific type of information collected in the Non-UT Health SA electronic study tool(s), where the information will be stored (e.g., on device, server), and how the research team will access the information. | | | | |
|  | | Provide details here:  Not applicable, see attached DAUR form  Not applicable, electronic study tool will not be used at UT Health SA  Not applicable, see attached NIH Data Management and Sharing Plan | | | | |
|  | | *\*Not required for exempt research* | | | | |
| **Item 16**  Does the study employ the use of telemedicine to conduct research visits*?*  *Research video conferencing involving a telemedicine/telehealth medical service delivered by a health professional licensed, certified, or entitled to practice in Texas and acting within their scope under Texas rules.* | | | | | | |
| No  Yes | | | | | | |
|  | | Confirm the understanding that all institutional requirements regarding the use of Telemedicine/Telehealth for research visits will be followed. Refer to [Telemedicine/Telehealth Medical Service State Regulatory Requirements guidance document](https://www.uthscsa.edu/sites/default/files/Services/forms/telemedicineresearchconsenting.pdf). | | | |

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| **Item 17**  Will the study team use emails to communicate ***clinical-related research*** info with UT Health SA research subjects*?* |
| No  Yes |

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| **Item 18**  Will the study team use text messages to communicate with UT Health SA research subjects*?* | |
| No  Yes | |
| Confirm that **only** institution-approved texting platforms will be used: *TigerConnect* or *Twilio* (through UT Health SA REDCap) |

| IRB review **Item 19** Do you plan to pay subjects? |  | No |
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|  | Yes - Submit [Participant Payment Form](https://www.uthscsa.edu/sites/default/files/Services/forms/inst_b.docx) |

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| IRB review **Item 20** Category of Funding  *If the research is being submitted to, supported by, or conducted in cooperation with an external or internal funding program, indicate the categories that apply. Check ALL applicable. If the research is supported by a subcontract, mark the funding source as the originator of funds.* | | | | | | | |
|  | | Not applicable - no funding | | | | | |
|  | | **Federal Funding** *(specify Department or Agency below)* | | | | | |
|  | |  | Agency for International Development |  | Dept of Energy | | |
|  | Consumer Product Safety Commission |  | Dept of Health & Human Services*(CDC, NIH, FDA, SAMHSA, HRSA)* | | |
|  | Dept of Agriculture |  | Dept of Housing and Urban Development | | |
|  | Dept of Commerce |  | Dept. of Justice (DOJ) | | |
|  | Dept of Defense (DoD) |  | Dept of Veterans Affairs (VA) | | |
|  | Dept of Education (DOE) |  | Dept of Transportation (DOT) | | |
|  | Environmental Protection Agency |  | National Aeronautics and Space Administration | | |
|  | National Science Foundation |  | Central Intelligence Agency | | |
|  | Other Federal Department or Agency. Specify: | | | | |
|  | Foreign | | | | |  | Private |
|  | Foundation | | | | |  | State |
|  | HSC Institutional Award | | | | |  | State University |
|  | Local Government | | | | |  | University |
| Pharmaceutical – Industry, Device or Biotech *Mark appropriate response below:*  Intellectual Property (IP) owned solely by Pharmaceutical Company  Intellectual Property (IP) shared by Investigator and Pharmaceutical Company  Intellectual Property (IP) owned solely by Investigator | | | | | | Other: | |

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| Funding Details **Item 21** Funding Details | | | | |
|  | Not applicable – no funding | | | |
| Yes  No | Are funds being provided through a sub-award? | | | |
| Name of agency or funding entity  *To add a row – select a row, copy & paste*  *To remove – select the row & delete* | Grant or Contract Title: | Granting/ Funding organization’s tracking number: | PI listed on the grant award or contract | Funding administered by:  *Insert:*  *-UTHSCSA OSP*  *-University Health*  *-STVHCS (VA)*  *-Biomedical Research Foundation of South Texas (BRFST)*  *-Other (provide name)* |
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| **Item 22** OtherResearch Activities (not included below)  *List of research procedures, items or services provided or tests that are directed by the study plan (e.g., chart review, questionnaire, etc.).*  *Submit data collection instruments (Form M, e.g., surveys, questionnaires, etc.) as applicable.* | | | | | | | |
| **N/A –** no other activities are directed by the study plan | | | | | | | |
| IRB review**Activities, Procedures, Services, Surveys, Chart Reviews, Tests, etc.**  *To add a row – select a row, copy & paste*  *To remove – select the row & delete* | Title: IRB review  # **Routine Care** Activities**3**  (per subject) | # **Research Only** Activities**4** (per subject) | Who is performing the activity / service? *(select all applicable)* | | | | |
| **Research Team**  List institution(s) where activity is performed  *(e.g., UT Health SA,*  *University Health, STVHCS)* | | **Non-Research Team; Study Site Employees**  List institutions where activity is performed  *(e.g., UT Health SA,*  *University Health, STVHCS)* | | Outside Source |
| Collect | Perform the analysis | Collect | Perform the analysis |
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| ***3*** *– Routine Care procedures = typically provided absent a research protocol;* ***4*** *– Research Only = lab services provided solely for the research* | | | | | | | |

EXEMPT Protocols only: **STOP** here

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| **Item 23** Research Activities | | | | |
| Research conducted during a routine hospitalization.  N/A | | | | |
| **University Health**  *University Health* *Specify Department or location*:  *Robert B. Green (RBG)* *Specify Clinic*:  *Texas Diabetes Unit (TDI) Specify Clinic*:  *Other Department or Clinic*: | | **South Texas Veterans Health Care System (STVHCS)**  *Audie Murphy Medical Center**Specify Department or location*:  *Barter Research Unit (BRU) IIMS-FIRST*  *FTOPC Specify Clinic*:  *Other Department or Clinic*: | | **Other Institution(s)** *Specify*:  Specify Department |
| Research requires hospitalization.  N/A | | | | |
| **University Health**  *University Health* *Specify Department or location*:  *Robert B. Green (RBG)* *Specify Clinic*:  *Texas Diabetes Unit (TDI) Specify Clinic*:  *Other Department or Clinic*: | | **South Texas Veterans Health Care System (STVHCS)**  *Audie Murphy Medical Center**Specify Department or location*:  *Barter Research Unit (BRU) IIMS-FIRST*  *FTOPC Specify Clinic*:  *Other Department or Clinic*: | | **Other Institution(s)** *Specify*:  Specify Department |
| Study procedures or follow up performed.  N/A | | | | |
| **UT Health SA**  *Mays Cancer Center*  *MARC* *Specify Clinic*:  *FIRST Outpatient Research Unit (FORU)*  *Dental School* *Specify Clinic*:  *Oral & Maxillofacial Surgery/Implant Clinic*  *Core Lab or Research Imaging Institute*  *Other Department* *Specify*: | **University Health**  *University Health* *Specify Department or location*:  *Robert B. Green (RBG)* *Specify Clinic*:  *Texas Diabetes Unit (TDI) Specify Clinic*:  *MARC Heart Station Number of visits*:  *Other Department or Clinic*: | | **South Texas Veterans Health Care System (STVHCS)**  *Audie Murphy Medical Center**Specify Department or location*:  *Barter Research Unit (BRU) IIMS-FIRST*  *FTOPC Specify Clinic*:  *Other Department or Clinic*: | **Other Institution(s)** *Specify*:  Specify Department |
| For each subject, how many outpatient research visits will be done at same time as a regularly scheduled appointment?  N/A | | | | |
| **UT Health SA**  *Mays Cancer Center*  *MARC* *Specify Clinic and Number of visits*:  *FIRST Outpatient Research Unit (FORU) Number of visits:*  *Dental School* *Specify Clinic and Number of visits*:  *Oral & Maxillofacial Surgery/Implant Clinic Number of visits:*  *Core Lab or Research Imaging Institute Number of visits:*  *Other Department* *Specify department and Number of visits*: | **University Health**  *University Health* *Specify department/location and Number of visits*:  *Robert B. Green (RBG)* *Specify Clinic and Number of visits*:  *Texas Diabetes Unit (TDI) Specify Clinic and Number of visits*:  *MARC Heart Station Number of visits*:  *Other Department or Clinic* *Specify department and Number of visits*: | | **South Texas Veterans Health Care System (STVHCS)**  *Audie Murphy Medical Center**Specify department/location and Number of visits*:  *Barter Research Unit (BRU) IIMS-FIRST Number of visits:*  *FTOPC* (Specify Clinic) *Specify Clinic and Number of visits*:        *Other Department or Clinic Specify department and Number of visits*: | **Other Institution(s) and department(s):**  Number of Visit(s): |
| For each subject, how many outpatient research visits will require an additional appointment?  N/A | | | | |
| **UT Health SA**  *Mays Cancer Center*  *MARC* *Specify Clinic and Number of visits*:  *FIRST Outpatient Research Unit (FORU) Number of visits:*  *Dental School* *Specify Clinic and Number of visits*:  *Oral & Maxillofacial Surgery/Implant Clinic Number of visits:*  *Core Lab or Research Imaging Institute Number of visits:*  *Other Department* *Specify department and Number of visits*: | **University Health**  *University Health* *Specify department/location and Number of visits*:  *Robert B. Green (RBG)* *Specify Clinic and Number of visits*:  *Texas Diabetes Unit (TDI) Specify Clinic and Number of visits*:  *MARC Heart Station Number of visits*:  *Other Department or Clinic* *Specify department and Number of visits*: | | **South Texas Veterans Health Care System (STVHCS)**  *Audie Murphy Medical Center**Specify department/location and Number of visits*:  *Barter Research Unit (BRU) IIMS-FIRST Number of visits:*  *FTOPC* (Specify Clinic) *Specify Clinic and Number of visits*:        *Other Department or Clinic Specify department and Number of visits*: | **Other Institution(s) and department(s):**  Number of Visit(s): |

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| **Item 24** Does this study have dietary restrictions (specialized meals or counseling) at STVHCS? | |
|  | No |
|  | Yes, *Specify*: |

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| IRB review **Item 25**Does the study plan dictate the use of any of the following (whether standard of care or investigational)? | **Yes** | **No**  *If No to all –*  *skip to Item 31* |
| A drug | *(list in Item 26)* |  |
| A biologic *(e.g., blood product, vaccine, virus, toxin, etc.)* | *(list in Item 26)* |  |
| A compound intended to affect structure or any function of the body | *(list in Item 26)* |  |
| A dietary supplement or substance generally recognized as safe (GRAS) | *(list in Item 26)* |  |
| A Device | *(list in Item 27)* |  |

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| **Item 26** List all protocol directed items below | Select one status choice below | | | | Additional IND Information | |
| **a)** List the **Drug(s), Biologic(s), Supplement(s), or other Compound(s)** directed by this protocol  *Insert the following for each drug:*   * **Name** (trade and generic), * **Dosage**, * **Route of administration**   *To add rows, use copy & paste* | **b)** FDA Approved?  *Insert either:*   * **Yes** * **No**   *Submit FDA approved package insert or investigator brochure* | **c)** Used in accordance with FDA approved labeling?  *Insert either:*   * **Yes** * **No** * **N/A (no FDA- approved labeling)** | **d)** Will study data be submitted to or held for inspection by the FDA for approval or a change in labeling, marketing or advertising?  *(any time – now or in the future)*  *Insert either:*   * **Yes** * **No** | **e)** Supplement or generally regarded as safe (GRAS) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease?  *Insert either:*   * **Yes** * **No** * **N/A (not a dietary supplement or GRAS)** | **f)** Status of IND  *Insert one of the following:*   * **Submitted on (insert date)** * **Approved (**insert IND number *and* include FDA IND letter**)** * **Exempt from IND** *– (Submit*[*Form O*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_o.docx)for UT IRB studies) | **g)** Name of the IND Holder (Sponsor)  *If the IND is held by a local investigator, submit an Inst-H* [*Local Investigator FDA-Sponsor form*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_inst_h.docx) |
| Insert response | Insert response | Insert response | Insert response | Insert response | Insert response | Insert response |

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| **Item 27** List all protocol directed items below | Select one status choice below | | | | Additional IDE Information | |
| **a)** List the **Devices** directed by this protocol  *Insert the following for each device:*  **Name** (trade and generic)  *To add rows, use copy & paste* | **b)** FDA Approved?  *Insert either:*   * **Yes** * **No** * **HUD *(used in clinical investigation)***   *Submit FDA approved package insert/ Device Manual* | **c)** Used in accordance with FDA approved labeling?  *Insert either:*   * **Yes** * **No** * **N/A (no FDA- approved labeling)** | **d)** Is the device being tested for safety and/or effectiveness?  *Insert either:*   * **Yes** * **No** | **e)** Will study data be submitted to or held for inspection by the FDA for approval or a change in labeling, marketing or advertising?  *(any time – now or in the future)*  *Insert either:*   * **Yes** * **No** | **f)** Status of IDE  *Insert either:*   * **Submitted to FDA on (insert date)** * **Approved (*insert*** *IDE number* ***and******submit*** *FDA IDE letter***)** * **Exempt from IDE submission to FDA** *(Submit*[FORM P](https://www.uthscsa.edu/sites/default/files/Services/forms/form_p.docx)for UT IRB studies) * Abbreviated IDE *for a NSR device**(Submit*[FORM P](https://www.uthscsa.edu/sites/default/files/Services/forms/form_p.docx) for UT IRB studies) * **N/A - FDA enforcement discretion** * **N/A – FDA Regulations do not apply** | **g)** Name of the IDE Holder (Sponsor)  *If the IDE is held by a local investigator, submit an Inst-H* [*Local Investigator FDA-Sponsor form*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_inst_h.docx) |
| Insert response | Insert response | Insert response | Insert response | Insert response | Insert response | Insert response |

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| **Item 28** Where will the drugs, biologics, or devices *(listed in item 26 and 27)* be stored and managed?  *(check all that apply)* | | |
|  | Hospital Pharmacy | If checked, list hospital(s): |
|  | Commercial Pharmacy | If checked, list pharmacy: |
|  | Investigational Drug Section of MCC |  |
|  | Standard of Care Device | If checked, list location(s): |
|  | Sponsor Managed Device | Provided only for procedure and promptly returned to Sponsor for storage upon completion of procedure.  Temporary location(s): |
|  | Other location(s) approved by 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.  Refer to [*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? *Affiliates only--Not a UT Health SA requirement* | | No  Yes, *attach letter or memorandum of understanding for originating institution & each receiving institution* [*Pharmacy LOU*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_inst_g.docx) |

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| **Protocol directed procedures, items, services or tests**  *Complete items 29-32 below by including all procedures directed by the research plan - including items or services provided as part of routine or conventional care and those needed to diagnose or treat research related complications.* | | | | | | |
|  | | | | | | |
| **Item 29** Drugs or devices *List all drugs or devices that are being directed by the protocol* | | | | | | |
|  | **N/A –** no other drug, biologic used as a drug, or devices | | | | | |
| IRB review**Drug or Device**  *To add a row – select a row, copy & paste*  *To remove – select the row & delete* | | Title: IRB review  *Select either:* Routine Care**1** **or**  Research Only**2** | Title: IRB review  # Encounters per subject | Who will administer the drug/device? *(select all applicable)* | | |
| **Research Team**  List institution(s) where drug/device will be administered/used *(e.g., UT Health SA, University Health, STVHCS)* | **Non-Research Team;**  **Study Site Employees** List institutions where drug/device will be administered/used *(e.g., UT Health SA, University Health, STVHCS)* | Commercial Source |
|  | |  |  |  |  |  |
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| ***1*** *– Routine Care = typically provided absent a research protocol;* ***2*** *– Research Only = required solely for the research* | | | | | | |

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| **Item 30** Who will be supplying the drug(s) or device(s) *(listed in item 26 and 27)* ? | | |
| **Drug/Device Name**  *To add a row – select a row, copy & paste*  *To remove – select the row & delete* | **Provided by** | **Paid by** |
|  | Hospital Stock; List hospital(s):  Sponsor  Prescription will be provided to fill at a commercial pharmacy | Hospital  Sponsor  Insurance/3rd Party |
|  | Hospital Stock; List hospital(s):  Sponsor  Prescription will be provided to fill at a commercial pharmacy | Hospital  Sponsor  Insurance/3rd Party |

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| **Item 31** Laboratory/Specimen collection  *List of laboratory tests that are dictated by the research protocol (e.g., CBC, CMP, PK, pregnancy test, etc.)* | | | | | | | | |
|  | **N/A –** this study does not involve lab tests | | | | | | | |
| IRB review**Laboratory procedures**  *Note: You may group tests that are always performed together*  *To add a row – select a row, copy & paste*  *To remove – select the row & delete* | | Title: IRB review  # Routine Care**3**  Procedures (per subject) | Title: IRB review  # Research Only**4** Procedures(per subject) | Who is performing the lab procedure? *(select all applicable)* | | | | |
| **Research Team**  List institution(s) where lab procedures will be performed *(e.g., UT Health SA,*  *University Health, STVHCS)* | | **Non-Research Team;**  **Study Site Employees**  List institutions where lab procedures will be performed *(e.g., UT Health SA, University Health, STVHCS)* | | Outside Source |
| Obtain specimen | Perform analysis | Obtain specimen | Perform analysis |
|  | |  |  |  |  |  |  |  |
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| ***3*** *– Routine Care procedures = typically provided absent a research protocol;* ***4*** *– Research Only = lab services provided solely for the research* | | | | | | | | |

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| **Item 32** Imaging  *List of imaging procedures that are dictated by the research protocol (e.g., x-ray, CT, MRI, US, etc.)* | | | | | | | | |
|  | **N/A –** this study does not involve imaging procedures | | | | | | | |
| IRB review**Imaging procedures**  *To add a row – select a row, copy & paste*  *To remove – select the row & delete* | | Title: IRB review  # Routine Care Procedures**3** (per subject) | Title: IRB review  # Research Only Procedures**4** (per subject) | Who is performing the imaging procedure? *(select all applicable)* | | | | |
| **Research Team**  List institution(s) where imaging will occur *(e.g., UT Health SA, University Health, STVHCS)* | | **Non-Research Team;**  **Study Site Employees**  List institutions where imaging will occur *(e.g., UT Health SA, University Health, STVHCS)* | | Outside Source |
| Obtain image | Perform analysis | Obtain image | Perform analysis |
|  | |  |  |  |  |  |  |  |
|  | |  |  |  |  |  |  |  |
| ***3*** *– Routine Care procedures = typically provided absent a research protocol;* ***4*** *– Research Only = lab services provided solely for the research* | | | | | | | | |

Warning: Do not delete the section break immediately below this text

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| IRB review **Item 33**  Research Team - Roles and Activities  ***Note: Submit*** [***Inst-M Personnel Form***](https://www.uthscsa.edu/sites/default/files/Services/forms/form_inst_m.docx) ***(list of all research team members by name)*** | | | |
| **Column A**  Build your research team below by **identifying key position titles**  *At a minimum, all studies must have a Principal Investigator.*  *Other suggested positions have been inserted below. Delete positions as appropriate to your study.*  **Position Title (DO NOT MODIFY POSITION TITLES)** | **Column B**  For each key position, list the roles & responsibilities that could be assigned to research team members in this position.  *Use the following codes to identify the responsibilities that are applicable for the role you created in Column A.*  *Not all roles are applicable to every study* | | **Column C**  For each position, list the minimum credentials and training required for any person assigned to this role.  *Use the following codes to identify the credentials & training for the role you created in Column A.*   1. Medical license (US) 2. Dental license (US) 3. RN license (US) 4. RPH license 5. license (US) 6. Good Clinical Practice (GCP) training 7. Research-related certification (e.g., CCRC) 8. Advanced academic degree 9. certification 10. certification 11. Specialized training for use of a device 12. Other: 13. Other:   [Training requirements](https://www.uthscsa.edu/vpr/services/approval-initiation/personnel/human)  [Scope of Practice requirements](https://www.uthscsa.edu/vpr/services/research-team-member-credentialing-and-scope-practice) |
| **General research responsibilities**   1. recruitment 2. assess inclusion and exclusion criteria 3. obtain informed consent 4. assist with the consent process 5. source documentation or case report form completion 6. perform physical examination 7. perform physical assessment 8. obtain medical history or evaluate concomitant medications 9. prescribe intervention being tested 10. administer intervention being tested 11. perform study procedures 12. adverse event inquiry and reporting 13. laboratory or other specimen handling 14. specimen shipping \*\* 15. investigational product dispensing & accountability 16. regulatory & essential documents, other record keeping or admin function 17. review private identifiable information 18. Direct REDCap access to identifiable study data (other than data entry) 19. posting, monitoring, responding to social media recruitment communications | **Oversight responsibilities**   1. directing the research team members and assessing compliance with study protocol 2. Lead PI - direct the study site PI(s) at other locations 3. determine significance of subject safety indicators (e.g., AE/SAEs, UADEs, SUSAR, UPs, etc.) 4. determine the significance of protocol deviations or violations 5. ensure the integrity of the data 6. Sponsor-Investigator monitoring and reporting \*\*\* 7. REDCap Study Administrator 8. Other: 9. Other: 10. Other: 11. Other:   \*\* Requires IATA Training / Safety-Shipping Infectious Substances, Clinical Specimens, and Dry Ice  \*\*\* Requires GCP for investigator-initiated studies of drugs, biologics or devices |
| **Principal Investigator (required)** | List applicable numbers from above: | | List applicable codes from above: |
| Co-PI *(delete as appropriate for study)* | List applicable numbers from above: | | List applicable codes from above: |
| Sub-Investigator *(delete as appropriate for study)* | List applicable numbers from above: | | List applicable codes from above: |
| Study Coordinator *(delete as appropriate for study)* | List applicable numbers from above: | | List applicable codes from above: |
| Study Nurse *(delete as appropriate for study)* | List applicable numbers from above: | | List applicable codes from above: |
| Research Assistant *(delete as appropriate for study)* | List applicable numbers from above: | | List applicable codes from above: |
| Data Coordinator *(delete as appropriate for study)* | List applicable numbers from above: | | List applicable codes from above: |
| Honest Broker *(delete as appropriate for study)* | List applicable numbers from above: | | List applicable codes from above: |
| Statistician *(delete as appropriate for study)* | List applicable numbers from above: | | List applicable codes from above: |

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| **For OIRB Use Only** | | |
| Name | Specialized skill or expertise in performing a high-risk research procedure required for this study\* |  |
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*\*IRB approval required to remove or replace this individual on this study*