UT Health San Antonio (UTHSA)

Institutional Clinical Trial Research Application

[*Clinical trials*](https://www.uthscsa.edu/vpr/services/glossary#Clinical-Trial) *must be reviewed and cleared by the Clinical Trials Office (CTO) before this institutional research application can be submitted.*

*CTO review is not applicable to human subjects research that does not meet the definition of a clinical trial.*

Items marked with the IRB review icon indicate fields that the institution and the UTHSA 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.

| UTHSA Tracking Number | |
| --- | --- |
| IRB review**Item 1** Title | CTMS#: |

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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

| **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 |  |

| 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. | |
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|  | 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 UTHSA, 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 | |
| Name of Study Site | Organization’s  Point of Contact (name) & contact information  *Note a Communication Plan is required for all non-affiliated study sites* | Site Engagement Questions | | |
| Name of study site  site under the direction of the PI  *For additional study sites, add rows and copy & paste* | Point of contact name and info | Are the study team members employed by the institution interacting with human subjects or accessing identifiable private information ([engaged in research](https://www.uthscsa.edu/vpr/services/glossary#Engaged-in-Research)) **OR** Are the non-study team members employed by the institution administering the study intervention being tested or evaluated for the study, obtaining consent from subjects, or performing services that merit professional recognition or publication privileges?  Yes, HSC IRB will be the reviewing IRB  Provide Number of subjects to be screened for eligibility:  Provide target enrollment number for completers:  What is the age range? *(if different, for each site)*  Yes,       IRB will be the reviewing IRB; Indicate the status of this organization’s IRB (or equivalent evidence of institutional support) approval.  No, The role of this site is limited to permitting the use of facilities for intervention or interaction with subjects by research team members who are employees from another institution. | | |

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| IRB review**Item 4a**UT Health San Antonio 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…) to be screened for eligibility: | | 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 the enrollment of subjects and collection of research blood samples. Clinical personnel will be in-serviced about the 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.  N/A | | | |
| **UTHSA**  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 *skip to Item 11*  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  I2B2 in conjunction with other sources  I2B2 is the **only** source of private information (all data is available from I2B2; there is 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 F**  Stored after study completed |
| **Identifiers** |  |  |  |  |  |
| **None** of the identifiers listed below ↓ | *If selected –* ***stop***  *Skip to Item 11* | *If selected –* ***stop***  *Skip to Item 10* | *If selected –* ***stop***  *Skip to Item 10* |  |  |
| 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)  *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 number, pathology specimen 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  *(None is checked in Columns B or C - Identifier Table (Item 6) --skip to* [*Item 10*](#Item11) | |
| 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  *(None is checked in Column C - Identifier Table (Item 6) -- skip to* [*Item 10*](#Item11) | |
|  | Not applicable, see attached DAUR form | |
| *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 and 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 San Antonio (even if collected from a non-Covered Entity) should be considered as a possible HIPAA disclosure.* | | | |
| Not applicable, not collecting protected health information (PHI) held by a covered entity | | | |
| **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., UTHSCSA, 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 *(PHI is not checked in Item 6) -- skip to* [*Item 11*](#Item12) | |
|  | Not applicable, using UTHSA 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)  *(None is checked in Column A - Identifier Table (*[*Item*](#Item7) *6)* |
| 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) | | | | | | |
| N/A, MCC Complion: e-Regulatory & Source Documentation for remote monitoring (listed in HIPAA authorization)  No, skip *to* [*Item 18*](#Item10)  Yes, select study tools that will be used *(check all that apply)*: | | | | | |  |
| UTHSA 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)*)* |
| UTHSA 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-UTHSA 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 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 UTHSA  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, *skip to next item*  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 San Antonio research subjects*?* |
| No, *skip to next item*  Yes |

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

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| IRB review**Item 19**Does the study plan dictate the use of any of the following?  *If No to all – skip to* [*Item 17*](#Item17)*.* | **Yes** | **No** |
| A drug | *(list in Item 14)* |  |
| A biologic *(e.g., blood product, vaccine, virus, toxin, etc.)* | *(list in Item 14)* |  |
| A compound intended to affect structure or any function of the body | *(list in Item 14)* |  |
| A dietary supplement or substance generally recognized as safe (GRAS) | *(list in Item 14)* |  |
| A Device | *(list in Item 15)* |  |

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| **Item 20** List all protocol directed items | 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 21** List all protocol directed items | 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)*)* * **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**](https://www.fda.gov/downloads/medicaldevices/.../ucm263366.pdf) * **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 22** Where will the drugs, biologics, or devices *(listed in item 14 and 15)* 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 UTHSA 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) |

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

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| IRB review **Item 21**  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*