**GENERAL INFORMATION SHEET**

**Note**: If you opened this form with your web browser, do not complete it until you first save it to your computer. Then close your web browser & open the form in Word. When using hyperlinks in this document, if you right-mouse click on a link and select “open hyperlink” the linked document will open in a separate window.

**1. Title of Project**: *(If applicable, use the exact title listed in the grant/contract application. You may include the study sponsor’s protocol number in the title.)*

|  |
| --- |
|  |

**2. Type of IRB review requested**:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Single patient** |

|  |
| --- |
|  |

 | Check both single and intermediate if it is anticipated that the FDA review of a single patient request may result in FDA approval of an intermediate sized group | **Intermediate sized group** |

|  |
| --- |
|  |

 | **Full Treatment Protocol** |

|  |
| --- |
|  |

 |
| **Single patient applications may skip all purple highlighted areas.**  | **Intermediate and Full applications must complete entire document including the purple highlighted areas.** |

1. **Name and Address of Principal Investigator (PI):**  (This is the primary contact information used by the IRB. Indicate where mail can most reliably reach the PI. If research is part of a multi-center study, the PI listed here should be the investigator responsible for the research conducted locally.)

|  |  |
| --- | --- |
| PI Name (Last Name, First Name, MI): |  |
| Employer(s): ***Example: UTHSCSA 50%, UHS 50%, or VA 50%)*** |  |
| Department: |  |
| Room # & Bldg: |  |
| Mail Code #**:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **PI’s Telephone**#:
 |  | PI’s Pager Number: |  |
|  |
| 1. PI’s e-mail address:
 |  | PI’s FAX Number: |  |
|  |
| 1. PI’s Position Title:
 |  |  |
|  |
| 1. PI’s Point of contact name & e-mail:
 |  | Point of Contact Phone Number: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **5. Age range of patients to be enrolled:**  |  |  |  |  |
| Age Range |

|  |
| --- |
| **6. Scope of the IRB Approval** – Select one of the four statements below that most accurately describes the scope of the study in relation to the Institutional Review Board |
| **Only the UTHSCSA IRB approval is being requested because:**  |
|

|  |
| --- |
|  |

 | the study only involves a **single site**  (UTHSCSA or an UTHSCSA Affiliate) | How many patients do you anticipate consenting?       |
|

|  |
| --- |
|  |

 | the treatment protocol involves [multiple sites](https://www.uthscsa.edu/vpr/services/glossary#Multisite-Research) **AND** the UTHSCSA IRB **IS** the IRB of record for all sites involved. | How many patients do you anticipate consenting?       |
| **UTHSCSA IRB is being requested locally, while other sites are reviewed by other IRBs** |
|

|  |
| --- |
|  |

 | This is a multi-center treatment protocol, the UTHSCSA IRB is being requested locally, while other sites are reviewed by other IRBs. | How many patients do you anticipate consenting locally?       |
|  |  | How many patients are being enrolled study-wide?       |

|  |
| --- |
| **7.**  **Categories of patients** - Indicate the categories of patients that will be treated. Depending on the items selected, you may be required to complete additional forms or meet additional requirements **Check ALL that apply**:  |
|

|  |
| --- |
|  |

 | [Decisionally Impaired](https://www.uthscsa.edu/vpr/services/glossary#Impaired-Decision-Making-Ability) [attach [Form T](https://www.uthscsa.edu/sites/default/files/Services/forms/form_t.docx)] |

|  |
| --- |
|  |

 | Pregnant Women [attach [Form U](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u.docx)] |
|

|  |
| --- |
|  |

 | Decisionally Impaired & [Institutionalized](https://www.uthscsa.edu/vpr/services/glossary#Institutionalized) [attach [Form T](https://www.uthscsa.edu/sites/default/files/Services/forms/form_t.docx)] |

|  |
| --- |
|  |

 | Fetal Material [attach [Form U](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u.docx)] |
|

|  |
| --- |
|  |

 | Individuals likely to have diminished decision-making capacity (not including incompetent or impaired decision making capacity)  |

|  |
| --- |
|  |

 | Other vulnerable population: \_\_\_\_\_\_\_\_\_\_ |
|

|  |
| --- |
|  |

 | [Children](https://www.uthscsa.edu/vpr/services/glossary#Children) (17 yrs or less), includes viable neonates [attach [Form W](https://www.uthscsa.edu/sites/default/files/Services/forms/form_w.docx)] |

|  |
| --- |
|  |

 | Neonates of uncertain viability ornonviable neonate [attach [Form U](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u.docx)] |
|

|  |
| --- |
|  |

 | Wards of the State [attach [Form W](https://www.uthscsa.edu/sites/default/files/Services/forms/form_w.docx)] |

|  |
| --- |
|  |

 | [Prisoners](https://www.uthscsa.edu/vpr/services/glossary#Prisoner) [attach [Form V](https://www.uthscsa.edu/sites/default/files/Services/forms/form_v.docx)] |

 **Intermediate sized group - Skip to question 10**

|  |
| --- |
| **8.**  **Indicate the targeted/planned enrollment***.*  *Select one*  |
|

|  |
| --- |
|  |

 | a. Patients will be enrolled in the order in which they qualify. No preference is given based on gender/race/ethnicity. **Skip to item 10** |
|

|  |
| --- |
|  |

 | b. Enrollment of patients will target the following breakdown relative to gender/race/ethnicity. **Complete item 9**. |

|  |
| --- |
| **9.**  **If 8b., complete table** |
|  |  **% Male**  |  **% Female** |  |  |  **% Male**  |  **% Female** |
| American Indian/ Alaskan Native |  |  |  | Asian or Pacific Islander  |  |  |
| Black-not Hispanic |  |  |  | Other [Type category here] |  |  |
| Hispanic |  |  |  | Other [Type category here] |  |  |
| White-not Hispanic |  |  |  | Other [Type category here] |  |  |

|  |
| --- |
| 10. **Drugs or Biologics** |
| **Does the study plan dictate the use of one of more drugs?** |
|  | **No.** – no drugs will be used in this study  |
|  | **Yes.** **If yes**, check all that apply |
|  |
|  | A drug, approved by the FDA will be used in a manner consistent with the FDA labeling. *(included in the research as part of good medical practice and is not a focus of the research)* [attach [Form O](https://www.uthscsa.edu/sites/default/files/Services/forms/form_o.docx), See Section 1] |
|  | A drug, approved by the FDA will be used in a manner consistent with the FDA labeling **AND** the study is intended to collect safety and effectiveness data for submission to the FDA [attach [Form O](https://www.uthscsa.edu/sites/default/files/Services/forms/form_o.docx), See Section 2] |
|  | A drug, approved by the FDA will be used in a manner not consistent with the FDA labeling. *(the use of the drug is a focus of the study)* [attach [Form O](https://www.uthscsa.edu/sites/default/files/Services/forms/form_o.docx)] |
|  | A drug that has not been approved by the FDA will be used and **the use of the drug is a focus of the study**.[attach [Form O](https://www.uthscsa.edu/sites/default/files/Services/forms/form_o.docx), See Section 3] |
|  | A radioactive drug that has not been approved by the FDA will be used to obtain basic information regarding the metabolism or regarding human physiology, pathophysiology, or biochemistry, however **the use of the drug is not a focus of the study**. [attach [Form O](https://www.uthscsa.edu/sites/default/files/Services/forms/form_o.docx), See Section 4] [Radioactive Drug Research Committee (RDRC) approval is also required – see [this item](#Other_committee_approvals) of this form.] |
| **Storage and Management of Drugs –** Where will the drugs be stored and managed?*(check all that apply)* |
|  |  | Hospital Pharmacy | If yes, list hospital(s) here: 🡪  |
|  |  | Investigational Drug Section of CTRC |  |
|  |  | Other location(s) approved by the Office of Clinical Research (OCR) | If yes, list OCRApproval number(s) here: 🡪  |

|  |
| --- |
| 11. **Devices**  |
| **Does the study plan dictate the use of one of more devices?** |
|  | **No.** – no devices will be used in this study  |
|  | **Yes.** **If yes**, check all that apply |
|  |
|  | A device, approved by the FDA will be used in a manner consistent with the FDA labeling |
|  | An *in vitro* diagnostic device (IVD) will be tested[attach [Form P](https://www.uthscsa.edu/sites/default/files/Services/forms/form_p.docx)] |
|  | A device, approved by the FDA will be tested with minor modifications **or** combined with other approved devices[attach [Form P](https://www.uthscsa.edu/sites/default/files/Services/forms/form_p.docx)] |
|  | A basic physiologic device will be used as a tool to investigate a physiological principle*(the device is used only to answer a research question)*[attach [Form P](https://www.uthscsa.edu/sites/default/files/Services/forms/form_p.docx)] |
|  | A device, approved by the FDA will be used for an indication not in the FDA labeling *(new indication)*[attach [Form P](https://www.uthscsa.edu/sites/default/files/Services/forms/form_p.docx)] |
|  | A device will be tested and the data will be used to support research or marketing applications to the FDA[attach [Form P](https://www.uthscsa.edu/sites/default/files/Services/forms/form_p.docx)] |
|  | A device that is not approved by the FDA *(investigational)* will be used[attach [Form P](https://www.uthscsa.edu/sites/default/files/Services/forms/form_p.docx)] |
| **Storage and Management of Devices –** Where will the devices be stored and managed?*(check all that apply)* |
|  |  | Hospital | If yes, list hospital(s) here: 🡪  |
|  |  | Other location(s) approved by the Office of Clinical Research (OCR) | If yes, list OCRApproval number(s) here: 🡪  |

|  |
| --- |
| 12. **Other products**  |
| **Are other products (i.e., food, medical food, dietary supplements, cosmetics) being tested to show health benefits?** |
|  | **No.**  |
|  | **Yes.** **If yes**, list here:  |
|  |

|  |
| --- |
| **13.**  **Additional information** - Indicate the items below that apply to this protocol. Depending on the items selected, you may be required to complete additional forms or meet additional requirements. **Check ALL that apply**.  |
|

|  |
| --- |
|  |

 | **Academic** Degree-Required Research  (Faculty advisor’s signature required on Form A) |

|  |
| --- |
|  |

 | **Gene** Transfer [see [Form Q-1](https://www.uthscsa.edu/sites/default/files/Services/forms/form_q-1.docx) ] |
|

|  |
| --- |
|  |

 | **Cancer** Clinical Trial  (CTRC Protocol Review Cmte approval required) |

|  |
| --- |
|  |

 | **HIV or Hepatitis** Screening [see [Guidance](https://www.uthscsa.edu/sites/default/files/Services/forms/communicablediseases.pdf)] |
|

|  |
| --- |
|  |

 | **Only Collecting** Biological Specimens or Data for a separate [bank or repository](https://www.uthscsa.edu/vpr/services/glossary#Repository) [attach a separate repository consent [Form E](https://www.uthscsa.edu/sites/default/files/Services/forms/form_e.doc)]  |

|  |
| --- |
|  |

 | **HIPAA** Waiver of Authorization [attach [Form J](https://www.uthscsa.edu/sites/default/files/Services/forms/form_j.docx)] |
|

|  |
| --- |
|  |

 | **Only Collecting** Biological Specimens or Data from **VA** patients for a separate bank (VA approval of bank required) [attach a separate VA repository consent [Form E-1](https://www.uthscsa.edu/sites/default/files/Services/forms/form_e-1.doc)] |

|  |
| --- |
|  |

 | **Waiver** of Requirement to Document Informed Consent  [attach [Form F](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f.docx)] |
|

|  |
| --- |
|  |

 | **Create** a local Repository or Data Registry[Use repository application] |

|  |
| --- |
|  |

 | Complete **Waiver** of Informed Consent  [attach [Form F](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f.docx)] |
|

|  |
| --- |
|  |

 | **Create** a local **VA** Repository or Data Registry (VA approval of bank required) [Use repository application] |

|  |
| --- |
|  |

 | Altering / **waiving** a portion of Informed Consent [attach [Form F](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f.docx)] |
|

|  |
| --- |
|  |

 | **Collect** Biological Specimens or data without Banking  |

|  |
| --- |
|  |

 | **Human Embryonic** Stem Cellsinsert NIH cell line reg # |
|

|  |
| --- |
|  |

 | [**Certificate** of Confidentiality](https://www.uthscsa.edu/vpr/services/glossary#Certificate-of-Confidentiality) (mention in consent and provide the approval) |

|  |
| --- |
|  |

 | **Data** & Safety Monitoring Board [attach [Form R](https://www.uthscsa.edu/sites/default/files/Services/forms/form_r.docx)] |

|  |
| --- |
| **14.a.** **Category of Funding** - If the investigational treatment is being submitted to, supported by, or conducted in cooperation with an external or internal funding program, indicate the categories that apply. **Check ALL that apply**  (“**§”** - *denotes a federal agency*): |
|

|  |
| --- |
|  |

 | **Not applicable - no external funding** |

|  |
| --- |
|  |

 | **Industry** (Other than Pharmaceutical Companies) |
|

|  |
| --- |
|  |

 | The PI is also the Sponsor under FDA requirements |

|  |
| --- |
|  |

 | **Internal** Institutional Grant Program |
|  |

|  |
| --- |
|  |

 | PI has completed mandatory PI-sponsor training |

|  |
| --- |
|  |

 | [National Science Foundation](http://www.nsf.gov/) **§** |
|  | [(HHS) Dept. of Health & Human Services](http://hhs.gov/) **§** (select applicable HHS agencies below) |

|  |
| --- |
|  |

 | **Pharmaceutical** Company |
|  |

|  |
| --- |
|  |

 | [(NIH) National Institutes of Health](http://www.nih.gov/) **§** |

|  |
| --- |
|  |

 | **Device or Biotech** Company |
|  |

|  |
| --- |
|  |

 | [(CDC) Center for Disease Control](http://www.cdc.gov/) **§** |

|  |
| --- |
|  |

 | Private Foundation or Association *(non-profit)* |
|  |

|  |
| --- |
|  |

 | [(HRSA) Health Resources and Services Administration](http://www.hrsa.gov/) **§** |

|  |
| --- |
|  |

 | State or local government |
|  |

|  |
| --- |
|  |

 | (SAMHSA) Substance Abuse and Mental Health Services Administration **§** |

|  |
| --- |
|  |

 | (VA) Veteran’s Affairs **§** [mark study as VA investigational treatment] |
|  |

|  |
| --- |
|  |

 | Other HHS: insert other HHS **§** |

|  |
| --- |
|  |

 | Other:       |
|

|  |
| --- |
|  |

 | UTHSCSA – Institute for Integration of Medicine and Science ([IIMS](http://iims.uthscsa.edu/)) **§** *(HHS funded)* |

|  |
| --- |
|  |

 | Federal Agencies not listed above **§**:       |

|  |
| --- |
| **14.b. Funding Details** - If a funding category was identified in Question 14.a., provide the specific funding source and/or cooperating organization(s): If your project is funded, please see the IRB application for additional attachments. |
|

|  |
| --- |
|  |

 | **Not applicable**  |
| **Specific agency or sponsor’s name**: |  |
| **Grant Title or Contract Title**: |  |
| **Granting organization or sponsor’s tracking number**: |  |
| **PI listed on the grant award or contract**: |  |
| **Local Project/Grant tracking #**  |   |
|  |

|  |
| --- |
| 15. **Safety Assessment**– Will research patients receive or be exposed to any of the following? See instructions in [brackets] related to additional committee approvals prior to IRB submission. |
| **a.** | **Ionizing Radiation** (radioactive materials, radiation generating equipment)Will patients receive radiation exposure at: 1) greater levels; 2) greater frequency; or 3) using a different mode than they would receive if they were not in this investigational treatment? [Radiation Safety Committee approval required – AND if materials not covered by IND, Radioactive Drug Research Committee approval required] |

|  |
| --- |
|  |

 | Yes |

|  |
| --- |
|  |

 | No |
| **b.** | **Non-ionizing Radiation** (UV light, class 3B/4 lasers, radiofrequency, microwave)Will patients receive non-ionizing radiation? |

|  |
| --- |
|  |

 | Yes |

|  |
| --- |
|  |

 | No |
| **c.** | **Biologic Hazards** (microbiologic or viral agents, pathogens, cell lines)Will patients be exposed to [biologic hazards](http://research.uthscsa.edu/safety/IBC.shtml) ?[Institutional Biosafety Committee approval required] |

|  |
| --- |
|  |

 | Yes |

|  |
| --- |
|  |

 | No |
| **d.** | **Vaccine Trials** Will patients receive an investigational vaccine? [Institutional Biosafety Committee & UT System Biosafety Committee approval required] |

|  |
| --- |
|  |

 | Yes |

|  |
| --- |
|  |

 | No |
| **e.** | **Recombinant DNA**Will patients receive [recombinant DNA](http://research.uthscsa.edu/safety/IBC.shtml)?[Institutional Biosafety Committee & UT System Biosafety Committee approval required] |

|  |
| --- |
|  |

 | Yes |

|  |
| --- |
|  |

 | No |
| **f.** | **Human Gene Transfer (Therapy) Protocol**Will patients receive Human Gene Therapy?[Institutional Biosafety Committee & UT System Biosafety Committee approval required] |

|  |
| --- |
|  |

 | Yes |

|  |
| --- |
|  |

 | No |
| If the answer to any of these questions is YES, your investigational treatment may require additional review by the appropriate safety committees at the applicable institutions. Contact the each institution for further guidance. [Click here](http://www.southtexas.va.gov/Research/Documents/ResearchProtocolSaftySurvey.docx) to access the VA Safety Survey needed for VA R&D applications if yes to any questions above (not needed for IRB). Committee approvals are addressed below. |

|  |
| --- |
| **16.** **Other Committee Approvals** - Does the investigational treatment fall under the purview of any other committee(s)? If you check any of the below committees, additional materials are required with your application submission. See IRB application for details, or contact OIRB for information (210) 567-8250. |
|  | **Committee** *Check all that apply* | committee approvals are required **before** IRB review | **Approval Date***(insert MM/DD/YY or pending)* |
|

|  |
| --- |
|  |

 | UTHSCSA Institutional Biosafety Committee | IBC #: |  |
|

|  |
| --- |
|  |

 | UTHSCSA Radiation Safety Committee  |  |  |
|

|  |
| --- |
|  |

 | Radioactive Drug Research Committee |  |  |
|

|  |
| --- |
|  |

 | CTRC Protocol Review Committee  | For Cancer Related Treatment Use  |  |
|

|  |
| --- |
|  |

 | Other: Insert name |  |  |

|  |
| --- |
| **17**. **Treatment Sites** - List all study sites with an existing IRB Authorization Agreement with the HSC IRB ([Affiliated Institutions](https://www.uthscsa.edu/vpr/services/glossary#Affiliated-Institution))Blue table is for Blanket Agreements & Green table is for Limited or Single Study Agreements. |

|  |
| --- |
| **Institutions Affiliated with the UTHSCSA IRB (IRB of Record)**“UTHSCSA IRB Affiliated Institutions”**Institutions with an existing Blanket IRB Agreement** *(blue table)* |
| **Check all that apply** | **Name of Institution / Treatment Site** *(list all participating sites below)* |
|  |  |
|

|  |
| --- |
|  |

 | **UTHSCSA**  |
|  |

|  |
| --- |
|  |

 | School of Medicine |
|  |

|  |
| --- |
|  |

 | CTRC at UTHSCSA |
|  |  |

|  |
| --- |
|  |

 | IDD |
|  |  |

|  |
| --- |
|  |

 | SWOG |
|  |  |

|  |
| --- |
|  |

 | click here to type Other |
|  |

|  |
| --- |
|  |

 | FIRST- Outpatient. Research Unit (FORU) IIMS-FIRST Program |
|  |

|  |
| --- |
|  |

 | Dental School |
|  |

|  |
| --- |
|  |

 | School of Nursing School |
|  |

|  |
| --- |
|  |

 | Graduate School of Biomedical Sciences |
|  |  |  |
|  |

|  |
| --- |
|  |

 | School of Health Professionals |
|  |

|  |
| --- |
|  |

 | Research Imaging Center |
|  |

|  |
| --- |
|  |

 | UT Medicine |
|  |

|  |
| --- |
|  |

 | click here to type Other |
|

|  |
| --- |
|  |

 | **College of Pharmacy, UT Austin (at UTHSCSA)** |
|

|  |
| --- |
|  |

 | **South Texas Veteran’s Healthcare System (STVHS)** |
|  |

|  |
| --- |
|  |

 | Audie Murphy Medical Center |
|  |

|  |
| --- |
|  |

 | Bartter Research Unit (BRU)IIMS-FIRST Program |
|  |

|  |
| --- |
|  |

 | Outpatient Clinics Division |
|  |

|  |
| --- |
|  |

 | Kerrville |
|

|  |
| --- |
|  |

 | **University Health System (UHS)** |
|  |

|  |
| --- |
|  |

 | University Hospital |
|  |

|  |
| --- |
|  |

 | University Health Center Downtown |
|  |

|  |
| --- |
|  |

 | University Center for Community Health (UCCH) |
|  |

|  |
| --- |
|  |

 | UCCH/Texas Diabetes Institute (TDI) |
|  |

|  |
| --- |
|  |

 | University Family Health Centers |
|  |

|  |
| --- |
|  |

 | UHS Breast Imaging Ctr / CTRC |
|  |

|  |
| --- |
|  |

 | Correctional Health Care Services |
|

|  |
| --- |
|  |

 | **Southwest Foundation for Biomedical Research (SFBR)** |
|

|  |
| --- |
|  |

 | **Southwest Research Institute (SwRI)** |

|  |
| --- |
| **Institutions with a Limited or Single study IRB Agreement** *(green table)* |
| **Check all that apply** | **Name of Institution / Site** *(list all participating sites below)* |
|
|

|  |
| --- |
|  |

 | **Christus Santa Rosa Health Care (CSRHC)**(Limited IRB Affiliation: UTHSCSA PI or FPR) |
|  |

|  |
| --- |
|  |

 | CHART Center (IIMS-FIRST Program) |
|

|  |
| --- |
|  |

 | CSRHS Family Practice Residency |
|

|  |
| --- |
|  |

 | Christus Santa Rosa Hospital |
|

|  |
| --- |
|  |

 | **Baptist Health System (BHS)**(Limited IRB Affiliation: UTHSCSA PI) |
|  |

|  |
| --- |
|  |

 | Baptist Medical Center |
|

|  |
| --- |
|  |

 | Northeast Baptist Hospital |
|

|  |
| --- |
|  |

 | North Central Baptist Hospital |
|

|  |
| --- |
|  |

 | Southeast Baptist Hospital |
|

|  |
| --- |
|  |

 | St Luke’s Baptist Hospital |
|

|  |
| --- |
|  |

 | **UT San Antonio (UTSA)** Collaborative research involving investigators from both UTSA and UTHSCSA |
|

|  |
| --- |
|  |

 | [**Other - Limited IRB Agreement**](https://www.uthscsa.edu/vpr/services/glossary#Affiliated-Institution)*(previously approved covering a defined category or group of studies (more than one study))*Name of Institution relying on HSC IRB: click here to type |
|

|  |
| --- |
|  |

 | [**Requesting a New Single Study IRB Agreement**](https://www.uthscsa.edu/vpr/services/glossary#Affiliated-Institution)*(not previously approved limited to this study))*Name of Institution relying on HSC IRB: click here to type [Complete Item 18 below if applicable] |

|  |
| --- |
| **18**. **Cooperative Off-Site Treatment** – sites without an existing IRB Authorization Agreement with the UTHSCSA IRB |
|  (1) | Are there other study sites under the direction of the PI listed in this application? |

|  |
| --- |
|  |

 | Yes |

|  |
| --- |
|  |

 | No |
| (2) | Are there other independent study sites collaborating with the PI listed in this application? *(Answer “NO” if NCI Cancer Trials or FDA regulated Clinical Trials)* |

|  |
| --- |
|  |

 | Yes |

|  |
| --- |
|  |

 | No |
| (3) | Are UTHSCSA IRB-affiliated investigators participating in research conducted completely at an institution(s) not covered by an existing UTHSCSA IRB Authorization Agreement? |

|  |
| --- |
|  |

 | Yes |  |

|  |
| --- |
|  |

 | No |
| (4) | Are there outside investigators (e.g., not otherwise affiliated) participating in research conducted at an institution(s) covered by a UTHSCSA IRB Authorization Agreement? |

|  |
| --- |
|  |

 | Yes |  |

|  |
| --- |
|  |

 | No |

|  |
| --- |
| **19. Institute for Integration of Medicine and Science (**[**IIMS**](http://iims.uthscsa.edu/)**)**Will you be using any of the IIMS-FIRST Program Clinical Sites?  |
|

|  |
| --- |
|  |

 | **Yes**, *contact IIMS-FIRST Program**for additional materials required with your application.* |

|  |
| --- |
|  |

 | **No** |

|  |
| --- |
| **20. Requirement for a Data Safety and Monitoring Plan (DSMP)****A. Is the overall risk of the research more than** [**minimal risk**](https://www.uthscsa.edu/vpr/services/glossary#Minimal-Risk)? |
|

|  |
| --- |
| X |

 | **Yes**, complete [Form R](https://www.uthscsa.edu/sites/default/files/Services/forms/form_r.docx)  (A DSMP is required by the IRB) |
| **B. Is a DSM Plan required by either the: (a) NIH** *(i.e., grant)* **or (b) FDA** *(i.e., research with an IND or IDE)* **?**  |
|

|  |
| --- |
| X |

 | **Yes**, complete [Form R](https://www.uthscsa.edu/sites/default/files/Services/forms/form_r.docx)   |