*The Research Application consists of Early Notification for Clinical Trials through the Clinical Trials portal, Institutional Application and UTHSCSA IRB Application (when using UTHSCSA IRB).*

*Clinical Trials must be reviewed and cleared by the Clinical Trials Office (CTO) before UTHSCSA IRB Application documents may be submitted. CTO review is not applicable to human subjects research that does not meet the definition of a* [*clinical trial*](https://www.uthscsa.edu/vpr/services/glossary#Clinical-Trial)*.*

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

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| **Item 1**  Is your study eligible for **Expedited Review**?  *Applicable during initial IRB review of a new study* | Yes – confirm that a completed [Form B-1](https://www.uthscsa.edu/sites/default/files/Services/forms/form_b-1.docx) *- Expedited Certification Form* is included with submission and continue with the rest of this form. |

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| **Item 2**  Special Confidentiality Considerations  *Select all applicable* | **Drug or Substance Abuse** research - - -*[consider obtaining a certificate of confidentiality]*  [Certificate of Confidentiality](https://www.uthscsa.edu/vpr/services/glossary#Certificate-of-Confidentiality) - -- -- -- - *[include statement in consent and provide the approval]*  **Genetic Research** - - - - - - - - - - - - - *[include risks of genetic research in consent & confidentiality plan in*  *Institutional Research Application -Data Security plan]*  **HIV or Hepatitis** Screening [See [Guidance](https://www.uthscsa.edu/sites/default/files/Services/forms/communicablediseases.pdf)]  **Documentation in the Medical Record** ----*[consider altering the study title to eliminate increased risk of*  *research participation disclosure]*  **N/A – no special confidentiality considerations** - *continue to* [*Item 3*](#Item3) |

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| **Item 3**  Data Safety Monitoring  *Select all applicable* | A Data Safety Monitoring Plan (DSMP) is required by either:  The NIH *(i.e. grant)* or the FDA *(i.e. research with IND or IDE)*  A Data Safety Monitoring **Plan** (DSMP) is required by:  The IRB *(because this is a greater than minimal risk study)*  A Data & Safety Monitoring **Board** (DSMB) will be used | *Submit*  [Form R](https://www.uthscsa.edu/sites/default/files/Services/forms/form_r.docx) - *Monitoring Participant Safety and Data Integrity* |
| N/A – none of the situations listed above apply | *continue to* [*Item 4*](#Item4) |

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| **Item 4**  Categories of subjects  *Select all applicable*  *Note for chart review research:*  *Answer based on whether subjects will fall into a category at the time you are reviewing the records.* | This study includes the following vulnerable populations:  Individuals with [Impaired decision-making ability](https://www.uthscsa.edu/vpr/services/glossary#Impaired-Decision-Making-Ability)  - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - --  Individuals with Impaired decision-making ability and [Institutionalized Individuals](https://www.uthscsa.edu/vpr/services/glossary#Institutionalized) - - - - - - - -  Pregnant Women *\*Pregnant Women will not be participants at the VA* - - - - - - - - - - - - - - - - - -  Pregnant Women *(for follow-up)* - - -- - - - - - -- - -- - - - - - -- - -- - - - - - -- - -- - - - - -- - -- - - - - - -    Fetal Material *\*Fetal Material will not be used at the VA* - - - - - - - - - - - - - - - - - - - - - - - - -  Neonates of uncertain viability or nonviable neonates - - - - - - - - - - - - - - - - - - - - - - - - - - - -  *\*Neonates will not be participants at the VA*  [Prisoners](https://www.uthscsa.edu/vpr/services/glossary#Prisoner) *\*Prisoners will not be participants at the VA* - - - - - - - - - - - - - - - ------------ - - - - - - - -  [Children](https://www.uthscsa.edu/vpr/services/glossary#Children) (17 yrs or less), includes viable neonates - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -  *\*Children will not be participants at the VA*  Wards of the State - - - - - - - - - - - - - - - - - - - - -- - - - - - - - - - - - - - - -- - - - - - - - - - - - - - - - - - - -  Students under the supervision of any investigator  Employees under the supervision of any investigator  Embryonic stem cell research  Other vulnerable population: | Submit  [Form T](https://www.uthscsa.edu/sites/default/files/Services/forms/form_t.docx)  [Form T](https://www.uthscsa.edu/sites/default/files/Services/forms/form_t.docx)  [Form U](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u.docx)  [Form U Follow and pregnant person consent](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u_follow_only.docx)  [Form U](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u.docx)  [Form U](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u.docx)  [Form V](https://www.uthscsa.edu/sites/default/files/Services/forms/form_v.docx)  [Form W](https://www.uthscsa.edu/sites/default/files/Services/forms/form_w.docx)  [Form W](https://www.uthscsa.edu/sites/default/files/Services/forms/form_w.docx) |

| **Item 5**  **Engagement of International Study Sites**  Are there any international study sites under the direction of the PI? | | No *there are no international study sites continue to* [*Item 6*](#Item6)  Yes *If yes list each location on a separate row below (also submit* [*Communication Plan*](https://www.uthscsa.edu/sites/default/files/Services/forms/communicationplan.docx)*)* | | |
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| Name of the Study Site  *To add rows use copy & paste* | Organization’s  Point of Contact (name) & contact information | Does this organization want the HSC IRB to review for them?  (insert *Yes or No)*  *If yes, contact the IRB Director;* | **If No**, indicate the status of this organization’s IRB (or equivalent evidence of institutional support) approval.  *(insert pending or the approval date)* | **If Yes,** provide **Name** and **contact** information of an individual (not affiliated with the study) who can provide information to the IRB about the research context at the international location |
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| **Item 6**  Research Consent & HIPAA Authorization Wizard  *The following items are designed to help you determine the appropriate waivers and documents.* | No – this study does not involve interaction or intervention with living  individuals - *continue to* [*Item 7*](#Item7)  Yes – this study involves interaction or intervention with living  individuals - *continue to* [*Item 8*](#Item8)  Both – this study involves interaction or intervention with living individuals or use of private information for one group but not for another - *continue to* [*Item 7*](#Item7) |

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| **Item 7**  Study does not involve interaction or intervention with living individuals or involves interaction or intervention with living individuals or use of private information for one group but not for another | |
| Will you obtain private identifiable information or identifiable biospecimens collected for other purposes? | No *continue to* [*next section*](#Item8)  Yes *Submit* [Form F](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f_chart.doc)  *(complete the Waiver of Consent section)*  Yes *but a Waiver of Consent is not needed because subjects will provide informed consent or informed consent will be waived as part of their participation in a contributing protocol (i.e. data coordinating center activities).* |

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| *If yes,*  Describe the source of the information: (medical records of patients seen in PI’s clinic, research records from HSC2010XXXH, clinical pathology materials, etc.) | Describe the source: |

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| *If yes,*  Does the information or biospecimens reviewed contain both health information and identifiers? | No *continue to [next section](#Item8)*  Yes *submit* [Form J](https://www.uthscsa.edu/sites/default/files/Services/forms/form_j.docx) *– HIPAA Waiver*  Yes *but a HIPPA Waiver is not needed because subjects will provide authorization or authorization will be waived as part of their participation in a contributing protocol (i.e. data coordinating center activities).* |
| Approximately how many separate records or biospecimens do you plan to obtain?  *If this is a multi-center study, indicate the total number of records you plan to obtain from all sites* |  |
| Will you obtain **anonymous tissue** specimens to test the safety or effectiveness of an *in vitro* diagnostic device? | | No *continue to* [*Item 8*](#Item8)  Yes *contact IRB Associate Director for applicable form(s)* |

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| **Item 8**  Issues related to **identifying** prospective subjects | |
| Do you plan to review existing information or biospecimens *(e.g., clinical, research records, clinical pathology materials)* to identify individuals who may be eligible to participate? | No *continue to* [*Item 9*](#Item9)  N/A  *the study does not involve interaction or intervention with living individuals Skip to* [*Item 17*](#Item17)  Yes *continue with completion with this item.* |

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| *If yes,*  Describe the source of the existing information or biospecimens: (medical records of patients seen in PI’s clinic, research records from HSC2010XXXH, clinical pathology materials etc.) | Describe the source: |

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| *If yes,*  Does the information reviewed contain PHI? | | No *continue to* [*Item 9*](#Item9)  Yes |
|  | *If yes, are you going to print, download, copy, save, data-scrape, or fax, or by any other means allow the data to leave the covered entity?* | No *continue to* [*Item 9*](#Item9)  Yes *submit* [Form J](https://www.uthscsa.edu/sites/default/files/Services/forms/form_j.docx) *– HIPAA Waiver* |

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| **Item 9**  Other ways to **identify** prospective subjects | | |
| Will individuals who are not members of the study team refer subjects to study staff? *(i.e., clinical providers)* | | No  Yes |
| Will participants self-identify? *(i.e., response to advertisements, word-of-mouth)* | | No  Yes |
| *If yes,*  Will recruitment materials be used? | No  Yes *(attach recruitment materials)* |

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| **Item 10**  First Contact - Recruitment  *select how and where initial contact will be made with potential subjects*; *list all applicable* | | | | | |
|  | N/A – this study does not involve interaction with living individuals  *continue to* [*Item 17*](#Item17) | | | | |
| ***How*** will contact be made: | | From study staff to participants | | From participants to study staff | Briefly describe the plan to contact subjects including differences between groups (if any) --*include details regarding relationship with subjects (i.e., members of treatment team will contact…)* |
| Telephone call | |  | |  |  |
| Email | |  | |  |  |
| Mail | |  | |  |  |
| Waiting room (public) | |  | |  |  |
| During scheduled visit (private) | |  | |  |  |
| Other method: | |  | |  |  |
| Will Social Media be used for recruitment?  No *continue to* [*Item 11*](#Item11)  Yes *(check all which apply and the remainder of this section)*  Facebook  Instagram  Twitter  Other: | | | Indicate the type of recruitment activity using social media  Static *(a post or advertisement where there is* ***no*** *anticipated interaction)*  Interactive *(a post or advertisement where interaction* ***is*** *anticipated)*  Interactive with public group(s):  Moderator approval is attached  A Moderator does not exist  Interactive with private group(s) – Include evidence of the group’s moderator approval  Private messaging | | |
| If interaction is planned, describe plans for responding to messages: | | | | | |
| Indicate how special VA rules will be applied:  *Refer to the VA Handbook for additional information* | | N/A – VA not a study site  Although email and telephone may be used as a first contact method at other study sites above, it will not be used for VA subjects. *A letter (with contact information) may be used to notify subjects but must be IRB reviewed/approved prior to use.*  Non-VA research advertisements will be posted at the VA facility, after facility director approval  Non-VA studies will not use Facebook as a method advertisement | | | |

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| **Item 11** Screening procedures | |
| 1. Will any screening procedures be completed by subjects prior to obtaining informed consent? | N/A not obtaining informed consent  No *– continue to* [*Item 12*](#Item12)  Yes |
| 1. *If yes,* what type(s) of screening procedures are planned? | *Select all applicable*  Withhold food and/or water overnight *– continue to* [*Item 11. c.*](#Item11c)  Withhold medication overnight: List *– continue to* [*Item 11. c.*](#Item11c)  Other: describe *– continue to* [*Item 11. c.*](#Item11c)  Screening questions *–skip to* [*Item11.d*](#Item11d)*.* |
| 1. *If yes,* how do you plan to handle consent for screening procedures? | Full (long) informed consent will be provided (either verbally or in writing), however a consent document will not be signed until after screening  *Submit* [Form F](http://research.uthscsa.edu/irb/Forms/Form%20F.docx) *(complete the Waiver of Documentation section)* |
| Abbreviated information about the study will be provided to subjects (not including all [required elements of consent](http://www.hhs.gov/ohrp/policy/consentckls.html)) and a consent document will not be signed until after screening  *Submit* [Form F](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f.docx) *(complete the Alteration of Consent and Waiver of Documentation sections and Waiver of Documentation sections* ***&*** *Submit a Script which covers all elements/altered elements of consent being discussed)* |
| 1. If recording the answers to screening questions – is the information health related?   Not applicable to withholding food, water, or medications overnight | No*– continue to* [*Item 12*](file:///Y:\Projects\Policy\Forms\IRB%20Application%20(formerly%20Step%202%20IRB)\2%20Revisions\UTHSCSA%20IRB%20Application%202018.08.06.docx#Item12)  Yes  *submit* [Form J](https://www.uthscsa.edu/sites/default/files/Services/forms/form_j.docx) *– HIPAA Waiver* |

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| **Item 12**  How will you consent subjects to participate in the research?  *Select all applicable* |  | Will not obtain consent from: *(select one)*  any participant  some participants | *If some participants selected, which ones?* | *Submit* [Form F](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f.docx)  *(complete the Waiver of Consent section)*  **OR**  *Waiver of Consent is not needed because subjects will provide informed consent or informed consent will be waived as part of their participation in a contributing protocol (i.e. data coordinating center activities).* |
| *If selected,*  Is the information collected for the study health information? | No  Yes  *submit* [Form J](https://www.uthscsa.edu/sites/default/files/Services/forms/form_j.docx) *– HIPAA Waiver*  Yes *but a HIPPA Waiver is not needed because subjects will provide authorization or a waiver of authorization will be obtained as part of their participation in a contributing protocol (i.e. data coordinating center activities).* |
|  | Will obtain consent **without a signature** | *If selected, select at least one of the following describing how you will obtain consent:*  Verbal in person  Telephone  Online  Survey (or other data collection tool)  Other | *submit* [Form F](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f.docx) *(complete the Waiver of Documentation section)*  *Also submit either:*  *the text of the information that will be provided (i.e., script, consent paragraph)*  *or an Information sheet -*[Form D-IS](https://www.uthscsa.edu/sites/default/files/Services/forms/information_sheet.doc) |
| *If selected,*  Is the information collected for the study health information? | No  Yes  *submit* [Form J](https://www.uthscsa.edu/sites/default/files/Services/forms/form_j.docx) *– HIPAA Waiver/Alteration for use of PHI* |
|  | Will **exclude** some of the [required elements of consent](http://www.hhs.gov/ohrp/policy/consentckls.html) in the consent form, information sheet, or consent process | | *submit* [Form F](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f.docx) *(complete the Alteration of Consent and Waiver of Documentation sections)* |
|  | Will obtain **full** consent using the **long** consent form for: | research at **non-VA site** | *submit* [Form D](https://www.uthscsa.edu/sites/default/files/Services/forms/form_d.docx) *-UTHSCSA Consent*  *(If collecting health information, ensure HIPAA section included in Form D)* |
| researchat **a VA site** | *submit* [Form D-1](https://www.uthscsa.edu/sites/default/files/Services/forms/form_d-1.doc)*- VA Consent (if study includes optional components, submit separate Form D-1 to the IRB and Form H-VA to VA R&D Office)* |
| only collecting biological specimens or data for a **bank or repository at non-VA site** | *submit* [Form E](https://www.uthscsa.edu/sites/default/files/Services/forms/form_e.doc)*- Repository Consent*  *(If collecting health information, ensure HIPAA section included in Form E)* |
| onlycollecting biological specimens or data for a **bank or repository at a VA site** | *submit* [Form E-1](https://www.uthscsa.edu/sites/default/files/Services/forms/form_e-1.doc)*- VA Repository Consent to the IRB and submit a Form H-VA to VA to the R&D Office* |
|  | Will use **deception** during consent – not providing subjects will all information about the study to prevent potential biases in the study | | *Review the* [*deception definition*](https://www.uthscsa.edu/vpr/services/glossary#Deception) *to determine whether to submit* [*Form F*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_f.docx) *(Alteration of Consent section)* |
|  | Will consent **pregnant partners** of participants | | *-submit* [*Pre-filled Form U for Pregnant Partners*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u_follow_only.docx), *and* *submit* [*Partner Consent Form*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_d-pp.doc) |
|  |  | Will obtain consent for a **research study** and an optional **sub-study** to bank specimens and/or data | sub-study is an **external** repository/registry | *submit* [Form E](https://www.uthscsa.edu/sites/default/files/Services/forms/form_e.doc)*- Repository Consent or review the* [*Informed Consent Guidance*](https://www.uthscsa.edu/sites/default/files/Services/forms/informedconsentguidancerepositories.docx) *for alternatives*  *(If collecting health information, ensure HIPAA section included in Form E)* |
| sub-study is an **internal** repository/registry | *Use the approved consent for existing Repository Study Insert HSC# for Repository:* |

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| **Item 13**  Initial  Consent Procedure  *Select all applicable* |  | The IRB Policy on [Obtaining Informed Consent](https://www.uthscsa.edu/sites/default/files/Services/forms/informedconsentprocess.pdf) will be followed |
|  | A different consent or documentation procedure will be used as follows: |

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| **Item 14**  Waiting period between informing the prospective subject and obtaining consent  *Select all applicable* |  | Prospective subjects can take as long as they wish to make a decision |
|  | Prospective subjects are expected to make a decision immediately or within a specified timeframe described here: |

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| **Item 15**  Informed Consent for Research Involving Non-English Speaking Subjects *Select one* |  | Only individuals who speak English will be enrolled | *Select one*  There is no expected direct benefit for those participating.  There is an expected direct benefit for those participating. Excluding non-English speaking individuals is acceptable because:  Describe: | | |
|  | Individuals who do not speak English will be enrolled | The translated consent will be submitted to the IRB:  *Select one* | | |
|  | Immediately following approval of the English consent. |  |
|  | Only after a potential non-English speaking participant is identified. Since this plan will delay enrollment pending IRB approval of a translated consent, provide justification that prospective non-English speaking subjects will not be excluded from beneficial research. | *Select one*  There is **no** expected direct benefit for those participating.  There is an expected direct benefit for those participating. Any delay in obtaining a translated consent is acceptable because:  Describe: |

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| **Item 16 Privacy Protections**  Describe the privacy protections that will be used to ensure privacy is protected during recruitment, consent, and the research interventions: | Recruitment | Consent | Research Intervention |
| Use of drapes or other barriers |  |  |  |
| Activities occur in a private room |  |  |  |
| Activities occur in a semi-private room |  |  |  |
| Other method: |  |  |  |

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| **Item 17**  Current Practice | N/A – this study does not test or evaluate an intervention *(Institutional Application– Item 24)* - *continue to* [*Item 19*](#Item19) |

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| *Describe the current local practice so that the IRB can understand how the research interventions compare.* | **-or-**  Describe current practice including any differences at your study sites: |

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| **Item 18**  Will a placebo be used in **place of standard therapy**? | No  Yes *submit* [Form O-2](https://www.uthscsa.edu/sites/default/files/Services/forms/form_o-2.docx) *– Use of Placebo in Place of Standard Therapy* |

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| **Item 19**  Safety precautions for greater than [minimal risk](https://www.uthscsa.edu/vpr/services/glossary#Minimal-Risk) intervention(s) being tested | N/A - this study does not test or evaluate a greater than minimal risk intervention - - *continue to* [*Item 20*](#Item20) |

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| List the greater then minimal risk study intervention(s) being tested  *To add rows use copy & paste* | Describe the procedures for protecting against or minimizing any potential risks | Where appropriate, discuss provisions for ensuring necessary medical or professional intervention or equipment provided in the event of adverse events, or unanticipated problems involving subjects. | If the safeguards will be different between/among groups, describe here |
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| **Item 20**  List the potential benefits of the study intervention(s) and/or monitoring procedure(s) likely to contribute to enrolled subjects’ well-being. If there are no benefits to enrolled subjects, state “none”.  \*All risks and discomforts associated with the intervention(s), study directed drugs, devices, and procedures will be listed in the informed consent document according to probability (likely, less likely or rare) and magnitude (serious or not serious). *If you do not have a consent document, you must complete the risk table in* [*Form BC (Protocol Template Form)*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_bc.docx)*.*  *To add rows use copy & paste* |
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| **Item 21**  Describe the potential benefits or importance of this study to others not enrolled in this study (i.e. what is the clinical relevance of this study): |
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| **Item 22**  **You must provide a detailed protocol with your IRB application.**  Indicate which of these documents you are including | Sponsor Study Protocol  Grant Application  [Protocol Template Form](https://www.uthscsa.edu/sites/default/files/Services/forms/form_bc.docx) |