**PROTOCOL FORM / RESEARCH DESCRIPTION**

If an item does not apply to your research project, indicate that the question is "**not applicable**” – do not leave sections blank

**Click once on the highlighted entry in each box to provide your response.** Click the item number/letter or word, if hyperlinked, for detailed instructions for that question. If your response requires inserting a table, picture, etc, you may need to first delete the box that surrounds the answer and then insert your table or other special document.

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| **1.** **Purpose and objectives.** *List the purpose and objectives:* |
| Insert purpose, objectives and research questions/hypotheses here. If you cut and paste from another document, make sure the excerpted material answers the question |

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| **2.** **Background.**   * Describe past experimental and/or clinical findings leading to the formulation of your study. * For research involving investigational drugs, describe the previously conducted animal and human studies. * For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. * Attach a copy of the approved labeling as a product package insert or from the Physician’s Desk Reference.   You may reference sponsor’s full protocol or grant application (section number and/or title) or if none, ensure background includes references.  Please respond to all components of this item, or clearly indicate which components are not applicable. | |
| 1. **Background** |
| Describe here or you may reference sponsor protocol or grant application by section |

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| 1. **Current practice** |
| Only for research involving a treatment intervention, describe the current local practice - what are the alternative treatments or procedures? |

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| **3. Study Design.**  Describe the study design (e.g., single/double blind, parallel, crossover, etc.) Consider inserting a scheme to visually present the study design. |
| Describe here. If you cut and paste from sponsor's protocol or grant application make sure the excerpted material answers the question |

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| **4. Research Plan / Description of the Research Methods:** |
| **4.a.** Provide a **comprehensive narrative** describing the **research methods**.  1) Provide the **order in which tests/procedures will be performed**,  2) Provide the **setting** for these events and a description of the **methods used to protect privacy** during the study.  3) Provide the **plan for data analysis** (include as applicable the **sample size calculation)**  Please respond to all components of this item, or clearly indicate which components are not applicable. |
| [Describe the order in which test/procedures will be performed and a description of the setting here]  [Describe the plan for data analysis here - address anayalysis for each specific aim]  [Describe the rationale for determining sample size here] |

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| **4.b. List of the study intervention(s) being tested or evaluated under this protocol** | | | | |
|  | **N/A -**  this study does not test or evaluate an intervention. Skip to item 4.d. | | | |
| **#** | **Study intervention(s) being tested or evaluated under the protocol**  *Add or delete rows as needed* | **Affiliate**  Place a check next to institution(s) where the  intervention will be performed | | **Local Standard Practice?**  Indicate whether the intervention is considered acceptable practice locally for applicable institutions |
| **1** | **Insert study intervention 1 here** | UTSW | Yes | |
| PHHS | Yes | |
| CMC | Yes | |
| THR | Yes | |
| TSRH | Yes | |
| Other: \_\_\_\_\_ | Yes | |
| **2** | **Insert study intervention 2 here** | UTSW | Yes | |
| PHHS | Yes | |
| CMC | Yes | |
| THR | Yes | |
| TSRH | Yes | |
| Other: \_\_\_\_\_ | Yes | |

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| **4.c.**  **Risk:Benefit Analysis of study interventions being tested or evaluated under this protocol**  For each study intervention identified in section 6b above, complete a risk:benefit analysis table.  *(Two tables are provided, copy & paste additional tables as needed or delete both tables if this study does not test an intervention)* |

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| **4.c.**  **Study Intervention #1**  Insert name used in 4.b. | | |
| **List each group exposed to this intervention on a separate line.**  (e.g., experimental, control, Arm A, Arm B, etc)  **Or** state All Groups/Subjects | | For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject’s well being). If there are no benefits, state “none”. | | |
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| **If you are requesting a Waiver of Informed Consent, complete the table below.**  If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**  List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).  (include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)  Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting. | | | | |
|  | **Not serious** | | | **Serious** |
| **Likely**  These risks are expected to occur in more than **20** out of **100** subjects. |  | | |  |
|  | **Not serious** | | | **Serious** |
| **Less likely**  These risks are expected to occur in **5-20** subjects or less out of **100** subjects. |  | | |  |
|  |  | | | **Serious** |
| **Rare**  These risks are expected to occur in less than **5** subjects out of **100** |  | | |  |

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| **4.c.**  **Study Intervention #1**  Insert name used in 4.b. | | |
| **List each group exposed to this intervention on a separate line.**  (e.g., experimental, control, Arm A, Arm B, etc)  **Or** state All Groups/Subjects | | For each group, list the **benefits** of this intervention. (Benefits can be directly from the intervention or from a monitoring procedure likely to contribute to the subject’s well being). If there are no benefits, state “none”. | | |
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| **If you are requesting a Waiver of Informed Consent, complete the table below.**  If you have a consent form, **list the reasonably foreseeable risks in the consent form (and do not complete this section).**  List the risks according to the probability (likely, less likely or rare) and magnitude (serious or not serious).  (include: 1) expected adverse events; 2) rare and serious adverse events; 3) all other psychological, social, legal harms)  Do not delete frequency. Frequency must be estimated because it will assist you with determining which adverse events will require prompt reporting. | | | | |
|  | **Not serious** | | | **Serious** |
| **Likely**  These risks are expected to occur in more than **20** out of **100** subjects. |  | | |  |
|  | **Not serious** | | | **Serious** |
| **Less likely**  These risks are expected to occur in **5-20** subjects or less out of **100** subjects. |  | | |  |
|  |  | | | **Serious** |
| **Rare**  These risks are expected to occur in less than **5** subjects out of **100** |  | | |  |

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|  | | **4.d**. List ALL other research procedures or componentsnot listed in table 4.b.  ***The combination of Tables 4b and 4d should account for all of the research procedures that will take place during this study.***  Consider grouping similar procedures under a single component (e.g., blood work, CT = safety assessments) | | |
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| **#** | **Research component**   * **individual procedures**   *example:*  **Eligibility Assessments**   * History and physical * Questionnaire * Laboratory tests   *Add or delete rows as needed* | **Column A**  **Local Standard Practice** Indicate the number of times each procedure will be performed as stipulated in the research plan **that would be performed if the participant were not participating in the study.** | **Column B**  **Research Only**  Indicate the number of times each procedure will be performed solely for research purposes *(meaning that the participant would not undergo the same number of procedures or would not undergo the procedure(s) at the same frequency if they were not participating in the study)* | **Column D**  **Risks**  **If you are requesting a Waiver of Informed Consent, complete the table below.**  List the reasonably expected risks for each procedure or group of procedures under the following categories as appropriate:   * Serious and likely; * Serious and less likely; * Serious and rare; * Not serious and likely; * Not serious and less likely |
| **1** | **Insert component 1 here** |  |  |  |
|  | Insert procedure here |  |  |  |
|  | Insert procedure here |  |  |  |
|  | Insert procedure here |  |  |  |
| **2** | **Insert component 2 here** |  |  |  |
|  | Insert procedure here |  |  |  |
|  | Insert procedure here |  |  |  |
|  | Insert procedure here |  |  |  |
| **3** | **Insert component 3 here** |  |  |  |
|  | Insert procedure here |  |  |  |
|  | Insert procedure here |  |  |  |
|  | Insert procedure here |  |  |  |
| **4** | **Insert component 4 here** |  |  |  |
|  | Insert procedure here |  |  |  |
|  | Insert procedure here |  |  |  |
|  | Insert procedure here |  |  |  |

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| **5. Safety Precautions.** *(Describe safeguards to address the serious risks listed above.)* | | | | |
| **a.** Describe the procedures for protecting against or minimizing any potential risks for each of the more than minimal risk research procedures listed above. | | | |
| Describe here | | | |
| **b.** Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. | | | |
| Describe here | | | |
| **c.** Will the safeguards be different between/among groups? | | | |
| |  | | --- | |  | | Yes | |  | | --- | |  | | No |
| If yes, describe here | | | |