**Protocol Template Form**

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| **Item 1 UTHSCSA Tracking Number** |  |

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| **Item 2 Abstract / Project Summary** | Provide a succinct and accurate description of the proposed research. State the purpose/aims. Describe concisely the research design and methods for achieving the stated goals. This section should be understandable to all members of the IRB, scientific and non-scientific.  **DO NOT EXCEED THE SPACE PROVIDED**. |
| Purpose/Objectives: Insert response here  Research Design/Plan: Insert response here  Methods: Insert response here  Clinical Relevance: Insert response here | |

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| **Item 3**  Background |  |
| *Describe past experimental and/or clinical findings leading to the formulation of your study.*  *For research involving unapproved drugs, describe animal and human studies.*  *For research that involves approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol.* | Insert background: Insert response here |
| **Item 4**  Purpose and rationale  *Insert purpose, objectives and research questions/hypotheses here.*  *If you cut and paste from another document, make sure the excerpted material answers the question* | Insert purpose: Insert response here |

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| **Item 5**  Study Population(s) Being Recruited  In your recruitment plan, how many different populations of prospective subjects do you plan to target? Provide number: | Identify the criteria for **inclusion**: | Identify the criteria for **exclusion**: |
| *e.g., a population can be individuals with type 2 diabetes controlled with diet and/or a population of healthy controls. Or a population can be individuals attending an education program, etc.*  List each different population on a separate row and provide a short descriptive **label**:  *(e.g., normal-healthy, diabetics, parents, children, etc.)*  *To add rows use copy & paste* |
| Insert response here | Insert response here | Insert response here |
| Insert response here | Insert response here | Insert response here |

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| **Item 6**  **Research Plan / Description of the Research Methods*****a.*** *Provide a* ***comprehensive narrative*** *describing the* ***research methods****.*  *Provide the* ***plan for data analysis*** *(include as applicable the* ***sample size calculation).*** |

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|  | Step-by-Step Methods: Insert response here |
| Data Analysis Plan: Insert response here |

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| **Item 7 Risks Section:**  Complete the following table to describe the risks of all **research procedures** listed in Step 2, Institutional Form (items 28-34). *Do not list risks of Routine care procedures here.*  N/A, Risks are described in the informed consent document – do not complete this table. | |
| **Research procedures**  *example:*   * History and physical * Questionnaire * Laboratory tests   *Add or delete rows as needed* | **Risks**  List the reasonably expected risks  under the following categories as appropriate: |
| Insert procedure here | Serious and likely;   * + Insert risk here or enter "none"   Serious and less likely;   * + Insert risk here or enter "none"   Serious and rare;   * + Insert risk here or enter "none"   Not serious and likely;   * + Insert risk here or enter "none"   Not serious and less likely   * + Insert risk here or enter "none" |
| Insert procedure here | Serious and likely;   * + Insert risk here or enter "none"   Serious and less likely;   * + Insert risk here or enter "none"   Serious and rare;   * + Insert risk here or enter "none"   Not serious and likely;   * + Insert risk here or enter "none"   Not serious and less likely   * Insert risk here or enter "none" |
| Insert procedure here | Serious and likely;   * + Insert risk here or enter "none"   Serious and less likely;   * + Insert risk here or enter "none"   Serious and rare;   * + Insert risk here or enter "none"   Not serious and likely;   * + Insert risk here or enter "none"   Not serious and less likely   * + Insert risk here or enter "none" |