**Protocol Template Form**

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

|  |  |
| --- | --- |
| **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 hereResearch Design/Plan: Insert response hereMethods: Insert response hereClinical Relevance: Insert response here |

|  |  |
| --- | --- |
| **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 |

|  |  |  |
| --- | --- | --- |
| **Item 5**Study Population(s) Being RecruitedIn 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 |

|  |
| --- |
| **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).*** |

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

|  |
| --- |
| **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 risksunder 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"
 |