**Form CT**

**UTHSA Clinical Trial Description**

This form is not mandatory. Other documents are acceptable if equivalent information is provided.

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| **UT Health San Antonio Tracking Number** *(internal use only)* |  | **1. Original Version Date** |  |
|  |  | **1.1. Revision Date(s)**  *add rows as needed* |  |

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| **2. Background**  *Briefly discuss the important literature relevant to the trial and that provides background for the trial. Include the importance of the trial and any relevant treatment issues or controversies*. |
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| **3. Objectives and Endpoints**  *All data points collected in the study should support an objective or have a regulatory purpose.*  *Complete the table – add rows as needed.* | | |
| **3.1. Objective(s)**  *Clearly and concisely define the primary and secondary outcomes.* | **3.2. Endpoint**  *Clearly define the endpoints.*  *(endpoints are the basis for concluding that the objective has been met).* | **3.3. Justification for Endpoint**  *Briefly explain why the endpoint(s) were chosen.* |
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| **4. Rationale**  *Briefly state the reason for conducting the clinical trial.* |
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| **5. Study Design** | | | | | | | | | | | | | | | | | | | | | |
| **5.1. Number of Groups/Arms** | | | | |  | | | **Group name(s)** | | | | |  | | | | | | | | |
| **5.2. Overall Design**  *Select all applicable* | | | | | | | | | | | | | | | | | | | | | |
|  | **Randomization** | | | | | | | |  | | **Cluster Randomized** | | | | | | | | | | |
|  | **Group-Sequential** | | | | | | | |  | | **Adaptive Design** | | | | | | | | | | |
|  | **Parallel Design** | | | | | | | |  | | **Placebo-Controlled** | | | | | | | | | | |
|  | **Superiority** | | | | | | | |  | | **Equivalence** | | | | | |  | | **Non-inferiority** | | |
| **Device** | |  | Pilot | | | | | |  | | Pivotal | | | | | |  | | Post-Approval | | |
| **Drug/Biologic** | |  | Phase 1 | |  | Phase 1/2 | | | |  | | Phase 2 | |  | Phase 2/3 |  | | Phase 3 | |  | Phase 4 |
|  | **Dose escalation** | | | *If yes, details →* | | |  | | | | | | | | | | | | | | |
|  | **Dose ranging** | | | *If yes, details →* | | |  | | | | | | | | | | | | | | |
|  | **Sub-studies** | | | *If yes, details →* | | |  | | | | | | | | | | | | | | |
| **5.3. Other Design Details**: | | | | | | | | | | | | | | | | | | | | | |

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| **6. Study Population** | | | | | |
| **6.1. Study Population(s) Label/Name**  *To add more populations – select a row, copy & paste* | **6.2. Identify the criteria for inclusion**  *The criteria that every potential participant must satisfy, to qualify for study entry.*  All individuals in this study population must meet all of the inclusion criteria in order to be eligible to participate in the study | | | | **6.3. Identify the criteria for exclusion**  *The characteristics that make an individual ineligible for study participation.*  All individuals in this study population meeting any of the exclusion criteria at baseline will be excluded from study participation. |
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| **6.4.**  **Will screen failures be allowed to re-screen at a later date?** |  | **No** |  | **Yes** *If yes, describe criteria below* ***↓*** | |
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| **7. Study Intervention(s) being tested or evaluated**  *This can include prevention, diagnostic or therapeutic interventions (e.g., drug or device) or educational, health services or basic science interventions (e.g., educational program, health care delivery model, or examining basic physiology)* |
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| **8. Protocol-Directed procedures, items, services or tests**  *List all procedures directed by the study plan - including items or services provided as part of routine or conventional care and those needed to diagnosis or treat research related complications.* |
| Important Note – The protocol directed procedures listed must match those in the Schedule of Activities (attachment) |
| **8.1. Drugs** *(trade and generic, dosage, route of administration)* |
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| **8.2. Devices** |
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| **8.3. Biologics** |
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| **8.4. Laboratory Tests** |
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| **8.5. Imaging Procedures** |
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| **8.6. Other Research Procedures** *(e.g., other safety and efficacy assessments.)* |
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| **8.7** **Attach a Schedule of Activities (SOA) Excel File**  [Download the Template here: [*Schedule of Activities*](http://research.uthscsa.edu/irb/Forms/Schedule%20of%20Events.xlsx)*]* | *Check to indicate that the*  *SOA Excel File is attached →* |  |

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| **9.** | **Preparation/Handling/ Storage/Accountability of Investigational Drug, Biologic, or Device**  *N/A* - *This study does not include any investigational products (e.g. drugs, devices or biologics)*  *N/A* - *An Investigator Brochure is attached*  *N/A - A Drug/Device Manual is attached* |
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| **9.1. Acquisition and accountability**  *State how the study intervention and control product will be provided to the investigator. Describe plans about how and by whom the study intervention will be distributed, including participation of a drug repository or pharmacy, and plans for disposal of expired or return of unused product.* | |
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| **9.2. Formulation, Appearance, Packaging, and Labeling**  *Describe the formulation, appearance, packaging, and labeling of the study intervention and control product, as supplied. Information in this section can usually be obtained from the IB or the package insert, or device labeling. This section should include the name of the manufacturer of the study intervention and control product.* | |
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| **9.3. Product Storage and Stability**  *Describe storage and stability requirements (e.g., protection from light, temperature, humidity) for the study intervention and control product. For studies in which multi-dose vials are utilized, provide additional information regarding stability and expiration time after initial use (e.g., the seal is broken).* | |
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| **9.4. Preparation**  *Describe the preparation of the study intervention and control product, including any preparation required by study staff and/or study participants. Include thawing, diluting, mixing, and reconstitution/preparation instructions in this section. For devices, include any relevant assembly or use instructions.* | |
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| **10. Study Intervention Additional Details** | |
| **10.1. Measures to Minimize Bias: Randomization and Blinding**  *This section should contain a description of randomization and blinding procedures (if applicable to the study design). It should include a description or a table that describes how study participants will be assigned to study groups, without being so specific that blinding or randomization might be compromised. Plans for the maintenance of trial randomization codes and appropriate blinding for the study should be discussed. The timing and procedures for planned and unplanned breaking of randomization codes should be included. Include a statement regarding when unblinding may occur and who may unblind. Provide the criteria for breaking the study blind or participant code. Discuss the circumstances in which the blind would be broken for an individual or for all participants (e.g., for serious adverse evets (SAEs)). Indicate to whom the intentional and unintentional breaking of the blind should be reported.* | |
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| **10.2. Study Intervention Compliance**  *Define how adherence to the protocol (e.g., administration of study intervention, use of device,) will be assessed, and verified (if applicable, e.g., plasma assays, electronic monitoring devices, daily diaries).* | |
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| **10.3. Permitted Concomitant Therapy**  *This section should be consistent with the medication restrictions in the inclusion/exclusion criteria previously listed. Describe how allowed concomitant therapy might affect the outcome (e.g., drug-drug interaction, direct effects on the study endpoints).* | |
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| **10.4.** | **Rescue Medicine**  *List all medications, treatments, and/or procedures that may be provided during the study for “rescue therapy” and relevant instructions.* |
|  | *N/A, no rescue medicine* |
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| **11. Study Intervention Discontinuation** |
| **11.1. Discontinuation of Study Intervention**  Describe the criteria for discontinuing the study intervention (e.g., halting rules), including any monitoring test(s) and associated clinical decision point(s). Include reasons for temporary discontinuation of the study intervention (e.g., type and quantity of adverse events), clearly stating the length of time, if applicable, and describe the data to be collected at the time of study intervention discontinuation and approaches for restarting administration of or re-challenging with study intervention. |
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| **11.2. Continued Follow-up Discontinuation of Study Intervention**  *Describe efforts that will be made to continue follow-up of participants who discontinue the study intervention, but remain in the study for follow-up, especially for safety and efficacy study endpoints (if applicable). Reasonable efforts must be made to undertake protocol-specified safety follow-up procedures to capture adverse events (AE), serious adverse events (SAE), and unanticipated problems involving risks to subjects or others (UPIRSOs).* |
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| **12. Statistical Considerations** |
| **12.1. Statistical Hypotheses**  *State the formal and testable null and alternative hypotheses for primary and key secondary endpoints, specifying the type of comparison (e.g., superiority, equivalence or non-inferiority, dose response) and time period for which each endpoint will be analyzed.* |
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| **12.2. Sample Size Determination**  *Include number of participants to recruit, screen, and enroll to have adequate power to test the key hypotheses for the study. Provide all information needed to validate your calculations and judge the feasibility of enrolling and following the necessary number of participants.* |
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| **12.3. Populations for Analyses**  *Clearly identify and describe the analysis datasets (e.g., which participants will be included in each).* |
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| **12.4. Statistical Analyses**  *Include analysis of primary efficacy endpoints, secondary endpoints, safety analyses, and any planned interim analyses* |
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