**PI Name:**

To enhance the real-world impact of the basic research to improve the clinical care of Veterans, BLR&D is instituting a new requirement for VA investigators applying for BLR&D funding to indicate the translational stages of their proposed project. Please review the definition of various Translational Pipeline (TP) Substages and Sub-Categories in the Table below, and the information in the Guidance document, prior to responding to the questions listed at the bottom:

|  |  |  |
| --- | --- | --- |
| **VA-ORD Translational Pipeline (TP) Stages\*** | | |
| **TP Stages** | **TP Substages** | **TP Substages Sub-Categories & Definition** |
| **T0: Basic Biomedical Research** | **T0-1: Disease Biology / pathology (Foundational Studies)** | **T0-1A: Studying  disease/condition to understand pathology and disease progression; biological, social and behavioral mechanisms underlying health or disease.** |
| **T0-1B: Developing / evaluating novel approach/strategy to address unmet clinical need.** |
| **T0-1C: Focused characterization of select pathway, metabolomic-, proteomic-, genomic - data & epidemiologic studies using existing large data sets etc. to identify key approach or target.** |
| **T0-2: Target Identification, Evaluation & Efficacy (Proof-of-Concept Studies)** | **T0-2A: Confirming role of target or approach in disease/condition** |
| **T0-2B: Developing therapeutic approaches based on target/ concept to improve a clinical condition; can include initial studies on lead molecule screening, developing prototype and assessments.** |
| **T0-2C: Proof-of-concept studies in animals to demonstrate feasibility of approach or therapy to address unmet clinical need.** |
| **T0-3: Validation to de-risk clinical development** | **T0-3A: Studies in additional disease model(s) to de-risk potential human translational concerns.** |
| **T0-3B: Validation of biomarkers, diagnostics etc. in different (gender, race etc.) populations to determine target group.** |
| **T0-3C: De-risking known FDA-recognized issues with the translational approach.** |
| **T0-4: IND/IDE Enabling and Developmental Studies Stage I (Generate Data for FDA INTERACT Meeting)** | **T0-4A: Lead/device isolation /development, optimization and selection.** |
| **T0-4B: Lead candidate or device selection & profiling manufacturing, stability, solubility, immunogenicity, PK/PD, ADME, preliminary GLP-Toxicology.** |
| **T0-4C: Pre-IND/IDE discussion with FDA. Develop plans for biomarkers, immunogenicity assays, etc. Develop plans for GMP manufacturing, and for clinical evaluation.** |
| **T0-5: IND/IDE-Enabling Studies Stage II** | **T0-5A: GLP-Tox, determine and convert safe animal dose to starting dose for FIH, GMP manufacturing, drug stability, validating biomarkers and assays for clinical trial, etc.** |
| **T0-5B: IND/IDE submission, any additional studies required by FDA for regulatory approval** |
| **T1: Translation to Humans** | **T1: Phase I safety trials** | **T1: First in human, dose escalation safety studies to determine recommended starting dose. Focuses on new methods of diagnosis, treatment, and prevention in a controlled environment.** |
| **T2: Translation to Patients** | **T2:  Human efficacy; Phase II and Phase III trials** | **T2-A: Phase II trial; Determine safety and efficacy of therapy in patients (dose response).** |
| **T2-B: Phase III larger clinical trials to establish efficacy & optimal use in humans.** |
| **T3: Translation to Practice** | **T3: Translation  to clinical  Practice** | **T3: Phase IV trials, Comparative effectiveness trials, pragmatic clinical trials, community based participatory research, dissemination and implementation research, etc. Health services research. Meta-analyses, and systematic reviews involving interventions. Development and implementation of evidenced-based guidelines, policies, and best practices.** |
| **T4: Translation to Communities** | **T4: Implementation studies** | **T4: Implementation, population monitoring of morbidity, mortality, health impact, Life cycle Management, Durability of Intervention. Wider dissemination/implementation of improved practices/interventions. Studies on impacts of policy and/or environmental change. Studies focusing on disease prevention through lifestyle and behavioral modifications.** |

**\* Modified From: Surkis et al. J Transl Med (2016) 14:235 "Classifying publications from the clinical and translational science award program along the translational research spectrum: a machine learning approach."**

**Question 1:** Please indicate below the TP Sub-Categories that best represents the translational stage(s) of your different Aims. Please note that different Aims may represent different TP Sub-Categories, and on occasion, an Aim may represent multiple TP Sub-Categories.

Aim 1: Aim 2: Aim 3: Aim 4:

**Question 2:** If the project is funded and the proposed Aims are successfully completed, will that move the Aims of the projects to another TP Sub-Category (please answer Yes, or No)?

Aim 1: Aim 2: Aim 3: Aim 4:

**Question 3:** For Renewing applications, please indicate the TP Sub-Categories for the Aims of the previous Award.

Aim 1: Aim 2: Aim 3: Aim 4: