**Internal Use Only**

**CP Number:**

**Study Concept Proposal Form**

|  |  |
| --- | --- |
| **CNICS Research Coordinating Committee (RCC):**Sonia Napravnik*,* PhD*, Co-Chair*Peter Hunt, MD, *Co-Chair*Amanda Willig, PhD, RD, *Co-Chair*Edward Cachay, MD, *Co-Chair* | **Submit this request to Mary Thielen***CNICS Project Coordinator*Email : mthielen@uabmc.eduPhone: (205) 895-5411 |
| **I. STUDY TITLE** |  |
| **II: DATE OF PROPOSAL** |  |
| **Please check to appropriate box(s) pertaining to your study:** |
|[ ]  Letter of Support requested[Online request form](https://sites.uab.edu/cnics/request-a-letter-of-support/) |[ ]  Data Elements included |[ ]  Patient Reported Outcomes included |[ ]  Specimens included |
| **I would like my Concept Proposal:** |
|[ ]  To be considered for a Full Review for implementation in CNICS\*I have reviewed the CNICS Guidelines and understand the estimated timeline. |[ ]  To explore study feasibility in CNICS\*If you checked this box, please download the “Study Feasibility Form” online and submit that instead. |
| **III. PROPOSING INVESTIGATOR** | Name/Degree:  |
|  | Current Position:  |
|  | Institution:  |
|  | Email Address:  |
|  |[ ]  Check the box if you meet the NIH criteria of Populations Underrepresented in the Extramural Scientific Workforce, [as described here](https://diversity.nih.gov/about-us/population-underrepresented).  (Optional) |
| **IV. CO-INVESTIGATORS** |  |
| **CNICS Collaborator and DATE of concept approval \***\**A member of the CNICS Leadership must be listed as a collaborator on all concept proposals* ***and*** *sign off on the final version prior to submission for review.* |  |
| **V. BACKGROUND AND RATIONALE***\*Include description of the unique contribution of this study to the literature* |  |
| **VI. APPLICATION TO CNICS SCIENTIFIC AGENDA** |  |
| **VII. SPECIFIC AIMS AND HYPOTHESES** |  |
| **VIII.** **Please insert your directed acyclic graph (DAG)**This is optional and applies to research that focuses on causation, interaction, attribution, or mediation.  It does not apply to research that is solely descriptive or focuses on prediction only. \*[Tutorial on directed acyclic graphs](https://sites.uab.edu/cnics/files/2022/02/Tutorial-on-directed-acyclic-graphs.pdf)[DAG drawing tool](http://www.dagitty.net/)\**Your CNICS collaborator and/or the CNICS Epidemiology & Biostatistics Core are available to assist with these.* |  |
| **IX. STUDY POPULATION** | Inclusion Criteria: |
|  | Exclusion Criteria: |
| **X. STUDY DESIGN AND STATISTICAL ANALYSIS** | Methods: |
|  | Outcome Variable(s): |
|  | Covariates: |
|  | Analytic Plan: |
| **XI. DATA ELEMENTS REQUESTED**  | Demographics: |
|  | Clinical Diagnoses: |
|  | Medications: |
|  | Laboratory Test Results: |
|  | Patient-Based Measures: |
|  | Additional Information: |
| **XII. BANKED SPECIMENS REQUESTED** **(if applicable)** |  |
| **XIII. BRIEF LABORATORY METHODOLOGY****(if applicable)** |  |
| **XIV. SAMPLE SIZE ESTIMATE** |  |
| **XV. EXTERNAL SUPPORT—Describe the proposed process for collecting additional data elements and the budget per unit capture or per site.***\*required for data not included in the dataset* |  |
| **XVI. IRB APPROVAL** | [ ] Not Applicable[ ] Uncertain if IRB is needed[ ] Pending[ ] Approved - Date: IRB Study number: |
| **Briefly describe how you learned about cnics** |  |