**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.edu  Phone: (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** | | |  | | | | | | | | | |