** LSUHSC CLINICAL AND TRANSLATIONAL RESEARCH CENTER (CTRC)**

**CTRC Protocol Application**

The CTRC requires that any investigators who utilize the CTRC acknowledge support in each publication, press release, or other document describing results of this project and must include an acknowledgment of the NIH support for this work – **“Supported in part by 1 U54 GM104940 from the National Institute of General Medical Sciences of the National**

**Institutes of Health which funds the Louisiana Clinical and Translational Science Center. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Protocol Title:**

**Principal Investigator:**

**Principal Investigator Department:**

**PI email:**

**PI phone:**

**Location/Address:**

**CoPI/s (please list ALL CoPIs on project):**

**LSUHSC Chart String #:**

**1) Proposal Funding Status:** ☐ Funded ☐ Pending ☐ Not Funded

**Funding Source:** ☐ Federal ☐ Industry-Initiated/ Industry-Sponsored

 ☐ College Department ☐ Investigator-Initiated/ Industry-Sponsored

 ☐ Foundation/ Organization ☐ Internal Funded Pilot Project

 **Sponsor Name:**

**Federal Grant Title:**

**Federal Grant Code:**

**Federal Grant PHS Sponsor:**

-OR-

**Federal Grant Non-PHS Sponsor:**

**Federal Grant Number:**

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**2) Research Involving: (Check all that apply):**

 ☐ Human Subjects ☐ Vertebrate Animals

 ☐ Investigational Products ☐ IP/Patents

**National Clinical Trials (NCT) #**

**IRB of Record:** ☐ LSUHSC NO ☐ Other:

**Has the study been IRB approved?** ☐ Yes ☐ No

**3) Is this a mentored study?** ☐ Yes ☐ No

**4) Translational Research** (Select One)

 ☐ T1 – Translation to Humans (testing basic science discoveries in humans for clinical effect &/or applicability)

 ☐ T2 – Translation to Patients (testing new interventions in human subjects under controlled environments to form the basis for clinical applications &

 evidence based guidelines)

 ☐ T3 – Translation to Practice (Research on application of new interventions/therapies, research yields knowledge on best ways to implement new

 medical interventions)

 ☐ T4 – Translation to Population or Policy Research (Interventions of factors/interactions that influence health of the populations; results in

 improved health of public)

 ☐ Other (Explain): Pilot Study

**5) Research Focus** (Check all that apply)

 ☐ Drug Delivery

 ☐ Testing Novel Mechanisms

 ☐ Novel Applications

 ☐ Screening/Diagnostic Testing

 ☐ Early Phase Human Subjects

 ☐ Utilizing Community-Based Research

 ☐ Repurposing of Drugs

 ☐ Other (Explain):

**6) Study Types (check all that apply):**

 ☐ Basic Research

 ☐ Pre-Clinical Research

 ☐ Clinical Research

 ☐ Population Research

 ☐ Pilot Study

 ☐ Other (Explain):

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**7) Disease State/Impact Area (You may check up to 4 boxes)**

 ☐ Aging ☐ Biomarkers

 ☐ Cancer ☐ Cardiovascular System/Diseases (CVD)

 ☐ Coronavirus; SaRS-CoV-2/COVID 19 ☐ Dementia or Alzheimer’s Ds

 ☐ Dental/ Oral; Maxillofacial; Eye, ENT ☐ Diabetes

 ☐ Emergency Medicine ☐ Endocrinology

 ☐ Environmental Illness; Disorders ☐ Epidemiology

 ☐ Genetics/Genomics ☐ GI/Digestive System; Hepatology

 ☐ Gynecology/Women’s & Maternal Health ☐ Health Disparities

 ☐ Hematology ☐ HIV/AIDS

 ☐ Immunology ☐ Infectious Disease; Microbiology

 ☐ Inflammation ☐ Information Science/Literacy; Telemed: Apps/Text/Video

 ☐ Metabolic Conditions/Metabolism ☐ Musculoskeletal System; Orthopedics

 ☐ Nephrology ☐ Nervous System; Neurology/Neuroscience

 ☐ Nutrition/Diet/Food ☐ Obesity

 ☐ Pathology ☐ Patient Care

 ☐ Pediatrics ☐ Physical Activity: Sports; Play; Athlete

 ☐ Populations Sciences; Health Outcomes Research ☐ Psychiatry/Psychology; Behavioral Sciences

 ☐ Respiratory System/Pulmonary Diseases ☐ Rheumatology

 ☐ Skin Ds; Dermatology ☐ Social Determinants of Health

 ☐ Stem Cell Research; Regenerative Medicine ☐ Substance Related Disorders (e.g. alcohol/drug)

 ☐ Surgery ☐ Underserved Populations

 ☐ Urology/Urologic Ds ☐ Vulnerable/Under-Represented Populations

 ☐ Other

**8) Project Association (check all that apply)**

 ☐ COBRE ☐ INBRE

 ☐ KCA Initiated Project/Study ☐ LA CaTS Community Scholar

 ☐ LA CaTS Pilot Grant Program Award ☐ LA CaTS Planning Grant Award

 ☐ LA CaTS Roadmap Scholar ☐ LA CaTS Visiting Scholar

 ☐ RCMI at Xavier University (NIH Research Centers in Minority Institutions Program)

 ☐ Other (Explain):

 ☐ None of the above

**9) Type of Collaboration** (check all that apply)

 ☐ Multi-disciplinary (involves 2 or more academic disciplines or fields of study)

 ☐ Multi-Institutional (2 or more investigators from different institutions)

 ☐ Inter-Institutional (2 or more investigators involved in 1 study & all involved are from same institution)

 ☐ Cross-Institutional/Multi-Site (1 study funded by more than 1 institution, investigators from different institutions & components of 1 study being

 Performed at various partner institutions)

 ☐ Single Investigator/Institution

**10) Ancillary Services/Resources Requested for this Project**

 ☐ Facility ☐ Core Laboratory

 ☐ Nursing ☐ LabCorp Laboratory

 ☐ Family Nurse Practitioner ☐ Pharmacy

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**Research Feasibility Checklist**

The feasibility checklist is completed by the Principal Investigator/study coordinator and submitted for review by the CTRC to determine the clinic’s ability to support study implementation. All submitted studies are evaluated prior to the initiation of any study activities within the clinic. Once a study is approved for implementation within the CTRC, an approval letter will be sent to the Principal Investigator/Coordinator.

Please submit a protocol document along with this completed form for CTRC review to Mary Meyaski, FNP-BC at mmeyas@lsuhsc.edu .

**Estimated Number of Subjects:**  **Estimated Number of Subjects Enrolled/Week:**

**Anticipated Enrollment Start Date:**  **Anticipated Enrollment End Date** **:**

**Study Site(s):** Will the study occur at multiple sites outside of LSUHSC CTRC? □ Yes □ No

 If yes, please check each study site:

 □ University Medical Center □ Home Health/Home Visits

 □ West Jefferson Medical Center □ LSU HealthCare Network Clinics

 □ Other**:**

Has a study coordinator been identified for implementation of the study? □ Yes □ No

If Yes, please provide study coordinator information:

**Coordinator Name:**

**Email:**

**Phone:**

Is the study coordinator capable of managing all study related activities and licensed accordingly: □ Yes □ No

If no, what services are you requesting from the CTRC:

(*some services may not be available at the time of request*)

□ Nursing service (phlebotomy only)

□ Additional Nursing (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

□ Study Coordination

□ Regulatory Management

□ Local Specimen Processing/Shipment □ Specimen Storage

□ PFTs (CTRC directed) □ Bodpod Measurement (CTRC directed)

□ Biopsy (CTRC assist) □ EKG (CTRC directed)

□ LabCorp (local lab service) □ PETH Testing (supplies provided by study)

□ Central Lab Processing/Shipment □ NIH Toolbox Testing (Cognitive Evaluation)

□ NP Services

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Please provide physician/NP back-up information should the Principal Investigator be unavailable:

**Name:**

**Email:**

**Phone:**

**Budget & Sponsor Obligations**

**MCA Cost Analysis Completed** □ Yes □ No **MCA Cost Analysis Accepted** □ Yes □ No

If the study is canceled prior to enrollment, will the sponsor/funding source pay for pre-study activities,

e.g., IRB preparation/submission, CTRC staff meetings, CTRC staff trainings, chart reviews, MCA preparation, etc.?

□ Yes □ No

Will the preliminary budget cover all estimated study related costs? □ Yes □ No

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Operational Information**

Will coordination with other departments/services be required for study visits/procedures: □ Yes □ No

If yes, please explain:

Will any special equipment be required for study implementation? □ Yes □ No

If yes, please explain:

If specimen processing is required, has an off-site lab been identified? □ Yes □ No

If specimen processing is required, have study staff members been identified to

 perform processing procedures off-site? □ Yes □ No

If specimens are collected in the CTRC, have study staff members been identified to

pick-up and transport collected specimens to the designated processing site? □ Yes □ No

If specimens are collected in the CTRC, have study staff members been identified to

arrange for specimen pick-up via designated couriers? □ Yes □ No

|  |
| --- |
| **Signatures** |

Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **CTRC Use Only (Do not complete this section)** |

Is the CTRC able to support and/or implement study activities as required by the

protocol and requested by the Principal Investigator? □ Yes □ No

Comments:

**CTRC Coordinator** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_