

CLINICAL AND TRANSLATIONAL RESEARCH CENTER
CTRC

Timetable for Receipt and Review of Applications

1. The CTRC Advisory Committee is scheduled to meet during the first week of every month, on Monday at 12:00 p.m. The Advisory Committee reviews and approves/disapproves all applications for use of the CTRC for research protocols.
2. Applications for use of the CTRC for research protocols (including appendix materials) are due in the Gina Currena, CTRC Administrator, by the 10th of the month for inclusion in the next Advisory Committee review agenda.
3. All applications submitted for consideration should be prepared according to the instructions provided (**they must be typed**). **Applications that do not comply with the requirements outlined for protocol submission will be returned to the principal investigator for revision and resubmission.** Please send **three (3) copies of the application and the research protocol** to Gina Currena, CTRC Administrator, 1430 Tulane Avenue, SL90, New Orleans, LA 70112, telephone number: 988-4000. In addition, please submit an electronic version to Gina Currena at gcurren@tulane.edu. Questions related to admission and special nursing procedures should be directed to Virginia Garrison, R.N., Nurse Manager, telephone number: 988-4000 or vgarris@tulane.edu.
4. The CTRC leadership will consider the expedited review of a protocol at any time *if* the investigator has identified a unique research subject whose timely cooperation needs to be secured and who would not otherwise be available, and untimely delay in enrolling the subject on-study would significantly jeopardize the investigator's research. In order to complete an expedited review, the CTRC Advisory Committee Chair will assign two Committee members to review the application and research protocol and make a determination about temporary approval. If temporary approval is provided, a full review by the Committee will take place at the next scheduled meeting. This procedure will be used *only in exceptional circumstances* as defined above. Institutional Review Board (IRB) approval must be obtained before the study is initiated.

Please complete the following information:

PRINCIPAL INVESTIGATOR: _____

P.I. SIGNATURE: _____

CO-PRINCIPAL INVESTIGATOR: _____

Co-P.I. SIGNATURE: _____

By signing above, I agree to cite CTRC support or resources utilized in all publications as follows:
"Supported in whole or in part by funds provided through the Louisiana Board of Regents RC/EEP."

**Clinical and Translational Research Center
Application for CTRC Use for Research Protocols**

Institutional Review Board (IRB) Number: _____ IRB Approval Period: _____

Anticipated start date : _____ Anticipated completion date: _____

Protocol Project Title:

Protocol Abstract:

Principal Investigator Name and Degrees: _____

Contact Information

Institution: _____

Department: _____

Mailing Address: _____

City, State, Zip: _____

Telephone: _____ Fax: _____

Email: _____

Co-Investigator(s) Name and Degrees: _____

Contact Information

Institution: _____

Department: _____

Mailing Address: _____

City, State, Zip: _____

Telephone: _____ Fax: _____

Email: _____

Co-Investigator(s) Name and Degrees: _____

Contact Information

Institution: _____

Department: _____

Mailing Address: _____

City, State, Zip: _____

Telephone: _____ Fax: _____

Email: _____

Study Contact Person/Study Coordinator: _____

Contact Information

Institution: _____

Department: _____

Mailing Address: _____

City, State, Zip: _____

Telephone: _____ Fax: _____

Email: _____

Is this a clinical trial as defined by the National Institutes of Health (NIH)? No Yes

Is this trial?	Single Center	Multicenter			
Pilot study	Phase I	Phase II	Phase III	Phase IV	

Is this trial?

Investigator Initiated

Industry Sponsored/Investigator Initiated

Industry Sponsored/Industry Initiated

Type of Study

A status: a) NIH or investigator initiated study and
b) Study visits are for research purposes only when hospitalization or clinic visit would otherwise not be necessary and
c) Charges will be paid by the CTTC or investigator's research funds

B status: a) NIH or investigator initiated study and
b) Inpatient days or outpatient visits will be done in context of clinical care for an active medical problem and
c) The charges are to be separated by clinical care and research. Clinical care charges are the financial responsibility of a third party payer or the patient and research procedures/interventions will be paid for by the study (CTTC or other grant funding)

- D status: a) Industry initiated study and
 b) may involve inpatient or outpatient visits and
 c) charges will be paid for by the industry sponsor

Research Support (Source of support related to this project)

No current outside funding sources are available to support this study

Outside funding exists to support this project (NIH, CDC, etc.)

NOTE: If outside funding exists, please attach budget submitted to funding agency and the Notice of Grant Award. CTRC support will not be approved until these documents are reviewed by the CTRC Finance Committee.

Name of Grant/Agency	Grant Number	Grant Principal Investigator	Total Direct Cost	Project Period

Anticipated duration of study: _____ (Please fill in appropriate tables below)

Total number of subjects to be enrolled: _____ Age range of subjects: _____

Is enrollment restricted by Gender, Race, or Age: No Yes

If yes, explain: _____

Estimated length of Outpatient Visit:

Less than an hour 1-3 hours 3-6 hours 6-10 hours More than 10 hours

Number of Inpatient admissions per subject: _____

Projected CTRC census for the first year of project

	# Subjects			Totals
Inpatient		x # days	=	
Scatter Beds		x # days	=	
Outpatient		x # days	=	

Projected CTRC census for the second year of project

	# Subjects			Totals
Inpatient		x # days	=	
Scatter Beds		x # days	=	
Outpatient		x # days	=	

Projected CTRC census for the third year of project

	# Subjects			Totals
Inpatient		x # days	=	
Scatter Beds		x # days	=	
Outpatient		x # days	=	

Projected CTRC census for the fourth year of project

	# Subjects			Totals
Inpatient		X # days	=	
Scatter Beds		X # days	=	
Outpatient		X # days	=	

Projected CTRC census for the fifth year of project

	# Subjects			Totals
Inpatient		X # days	=	
Scatter Beds		X # days	=	
Outpatient		X # days	=	

Identify the area(s) where subjects will be treated or cared for:

Children’s Hospital of New Orleans

HOP Clinic

Tulane University Hospital and Clinic

LSU Interim Hospital (University Hospital)

Other Specify: _____

CTRC Resources Requested for this Project

Pharmacy

If you have never done so for this protocol, please contact Katie Nguyen by email, knguy3@lsuhsc.edu or at 504-903-0383.

Bionutrition

If Bionutrition support is requested and you have never done so for this protocol, please contact the Bionutrition Manager, Angela Cemo by email, acemo@lsuhsc.edu or at 504-988-4000.

Bionutritional Needs:

Diet Instruction

Specify: _____

Nutritional Analysis

Specify: _____

Nutritional Assessment of Patient

Specify: _____

Special Diet

Specify: _____

Biostatistician

If Biostatistics support is requested and you have never done so for this protocol, please contact the Biostatistics Core, Dr. Leann Myers by email, myersl@tulane.edu or at 504-988-7855 prior to submission of this application.

Core Ancillary Tests

If ancillary tests are requested, please complete the Ancillary Tests table below.

Research Subject Advocate

If you have any questions regarding the Data Safety Monitoring Plan, please contact the CTRC Research Subject Advocate, Mary Meyaski-Schluter by email, mmeyask@tulane.edu or at 504-988-4000.

Nursing

If you have never done so for this protocol, please contact the CTRC Nurse Manager, Virginia Garrison, RN, by email, vgarris@tulane.edu or at 504-988-4000.

Nursing Services Being Requested:

- Scheduling, check-in
- Physical exam/history
- Questionnaires
- IV Placement/Blood draws
- Administration of study drug or medications
- Chemotherapy
- Other (please specify): _____

Nursing Intensity:

- Level I:** Basic single or several blood draws and vital signs, height, and weight. Patient requires minimal nursing observation and patient time is from 30-60 minute time periods.
- Level II:** Multiple blood draws, multiple ECGs, multiple vital signs, starting an IV, drug infusion, questionnaires, and moderate nursing observation from 1 to 4 hours.
- Level III:** Concentrated nursing care and observation which may include all or parts of the other Levels that may last up to 4 hours. Examples: urine collection, frequent vital signs, blood draws, administering IV meds).
- Level IV:** One-on-one concentrated nursing care and observation for more than 4 hours. This may or may not include all aspects of the other Levels.

Core Laboratory If Core Laboratory support is requested, please complete the table below. For questions, please contact the CTRC Core Laboratory Director, Dr. Shanker Japa by email, japashan@tulane.edu or at 504-988-4011.

Core Laboratory Use Requested in the first year (complete only for tests requested of the CTRC Core Laboratory, not an outside laboratory)

<u>TEST</u>	<u>Number of Samples/Year</u>	<u>Total</u>
Sample processing (Plasma, Serum, Buffy coat, etc.)	_____	_____
Smears	_____	_____
Whole Blood	_____	_____
Urine aliquots	_____	_____
Storage of samples (short and long-term)	_____	_____
Shipping of samples*	_____	_____
DNA extraction	_____	_____
RNA extraction	_____	_____
PCR	_____	_____
RT-PCR	_____	_____
Genotyping	_____	_____
Gene expression analysis	_____	_____
Pathway specific gene array(s)	_____	_____
ELISA	_____	_____
Other (please describe)	_____	_____

* If you are requesting the CTRC Core Laboratory to ship your specimens, please specify on the budget form who will cover the cost of shipping, boxes, and dry ice if applicable.

Ancillary Test Table (Please modify to suit your study)
(PLEASE MARK TESTS THAT ARE STANDARD OF CARE)

Test	S.O.C.	Cost/Test	Number of Subjects Per Year	# Number of Tests per Subject per Year	Total Cost per Year	\$ Amount from Your Funds	\$ Amount Requested from CTRC
Laboratory Tests:							
CBC							
CBC w/ diff & platelets							
Basic Metabolic panel							
CMP							
Urinalysis - Micro							
Urinalysis - Macro							
Lipid panel							
Liver panel							
Hemoglobin A1C							
Other Laboratory Tests:							
Radiology Tests:							
Chest x-ray							
CT scan							
MRI							
U/S							
Pet Scan							
Bone Scan							
DEXA Scan							
Other Radiology Tests:							
Cardiologic Tests:							
EKG							
Echo							
Other Cardiologic Tests:							
Other Tests:							

For Industry Sponsored projects please provide the following information:

Name/title of person to whom bills for reimbursement should be sent to: _____

Physical Address: _____

Telephone #: _____ Fax #: _____

Email Address: _____

CLINICAL AND TRANSLATIONAL RESEARCH PROPOSAL

- A. **SPECIFIC AIMS:** State the hypothesis and specific aims of this project. List the long-term objectives and what the proposed research will accomplish.
- B. **BACKGROUND AND SIGNIFICANCE:** Describe the background leading to this study, evaluate existing knowledge, and identify gaps, which this study will fill. State the importance of the research by relating the specific aims to the long-term objectives.
- C. **PRELIMINARY STUDIES/PROGRESS REPORT:** Provide an account of previous studies and/or information that establishes the experience and competence of the investigator to pursue the project.
- D. **RESEARCH DESIGN, METHODS, and STATISTICS:**
 - 1. Describe the research design, including procedures.
 - 2. Describe specific details of when and how the CTRC will be used, as well as what resources are requested. Provide a flow diagram or timetable.
 - 3. Describe the statistical methods, including design, sample size justification, and proposed analysis. For help, please contact the CTRC Biostatistical Department.
- E. **PROTECTION OF HUMAN SUBJECTS:**
 - 1. Risks to the Subjects
 - a. Human subjects involvement and characteristics: Provide number, age range, and health status of the subject population. Identify criteria for inclusion or exclusion.
 - b. Identify sources of research material in the form of specimens, records, or data.
 - c. Describe potential risks, assess likelihood and seriousness.
 - 2. Adequacy of Protection Against Risks
 - a. Describe plans for subject recruitment and consent procedures.
 - b. Describe procedures for the protection against or minimizing potential risks.
 - 3. Describe potential benefits and importance to subjects and others.
 - 4. Describe importance of knowledge to be gained.
- F. **WOMEN AND MINORITY INCLUSION IN CLINICAL RESEARCH**
 - 1. A statement regarding inclusion of women.
 - 2. A statement regarding inclusion of children (under age 21).
 - 3. A statement regarding the inclusion of minorities.
- G. **DATA AND SAFETY MONITORING PLAN**
- H. **REFERENCES**
- I. **JUSTIFICATION FOR UTILIZATION OF THE CTRC:** Provide a summary describing the necessity of CTRC resources.