CLINICAL RESEARCH UNIT (CRU) PROTOCOL APPLICATION INFORMATION PAGE

Each protocol must be reviewed and approved by the Clinical Research Center Administrative Review Committee. All studies must also be approved by the MSSM Program for the Protection of Human Subjects Institutional Review Board (IRB). Submissions to both Committees may be made concurrently.

Important!

An electronic version of all documents in either Word or PDF format can be emailed to Joanne Zephir, Program Coordinator, at Joanne.Zephir@mssm.edu

Once the protocol is IRB approved and you have dated consent forms please submit them.

IT IS STRONGLY RECOMMENDED THAT CRC ADMINISTRATION BE CONTACTED WELL IN ADVANCE OF PROTOCOL SUBMISSION.

Mount Sinai

CLINICAL RESEARCH UNIT PROTOCOL APPLICATION

GCO #:

PROTOCOL TITLE:

Original CRU Submission Date: **CRU Resubmission Date:**

Principal Investigator:
Rank:
Tel. #: **Pg. #:**
Department: **Box #:**

Co-Investigator(s):
Rank:
Tel. #: **Pg. #:**

Co-Investigator(s):
Rank:
Tel. #: **Pg. #:**

Coordinator:
Tel. #:

List Investigator(s) who will directly respond to medical concerns:
Investigator: **Tel. #:** **Pg. #:**
Investigator: **Tel. #:** **Pg. #:**

Study will include services being billed to insurance?Select One

Funding Information
☐ **Federal/Foundation/Internal**
☐**Industry Associated**
☐**Industry Initiated**
☐**Investigator Initiated**

Sponsor/Funder:
Grant Number:
Project/Award Period:
Award Amount:
***Study Fund Account:**
***Alternate departmental /fund account, if study fund is not yet established:**

**** A fund number is required before the CRC will initiate any procedures.***

VISIT PERSONNEL AND PROCEDURES

CRU WALK-IN PHLEBOTOMY SERVICE

☐ **Phlebotomy Only** (Unscheduled, walk-in basis) **This service is currently available Monday – Friday 9:00 AM to 4:30 PM** (Closed on hospital holidays)	Tubes: ☐ Returned to Coordinator ☐ Processed by CRU staff	**# of Blood Draws Expected:**

****Walk-in Phlebotomy is available for blood sampling, where the study team is taking the blood to their lab for processing, and/or safety bloods, where the participant's demographics are already available for registration in Epic.****

CRU AMBULATORY VISITS

Personnel:	Hour(s)/visit:	**Procedures:**	# Times/Frequency or Hour(s)/visit:
☐ CRU Clinical Staff		☐ Drug Administration:	
☐ None/Space Only		☐ Infusion ☐ Injection ☐ Oral	
If space only, please describe the responsibilities of the study team: _____		☐ IV placement	
_____ _____		☐ Blood Draw ☐ One-time ☐ Serial	
		☐ Specimen Processing: ☐ Centrifuge ☐ Slide Preparation	
		☐ Monitoring	
		☐ Physical Exam	
		☐ Vitals	
		☐ Monitoring/Observation	
		☐ Oral Food Challenge	
		☐ PK sampling	
		☐ Other, please specify below: _____	

TARGETED/PLANNED ENROLLMENT: **Number of Subjects at Mount Sinai**
If multicenter study, total number of subjects

Study Length (ex., "1 Year"): ☐ **Total # of Patients to be Evaluated:** ☐

Age Range of Patients	Min:	Max:

Outpatient visits / pt: ☐ **Hours /visit:** ☐

Please provide an explanation of any unique situations.

Time of day required for testing:

☐ Morning/Fasting: ☐ Any time: ☐ Other (Specify):

** Please note there is greater flexibility in scheduling in the afternoon.

Special nursing requirements:

Special infection control requirements:	☐ Yes	☐ No	If yes, specify:
Falls precaution:	☐ Yes	☐ No	
Seizure precaution:	☐ Yes	☐ No	
Patients can care for selves:	☐ Yes	☐ No	
Require nursing assistance:	☐ Yes	☐ No	If yes, specify:

Has approval from IRB been received? ☐ Yes ☐ No ☐ Pending

Dates of approval:

Laboratory/Procedure requirements: Please list **ALL** laboratory tests (blood, urine, etc.) and procedures (EKG, physical exam, etc.) to be performed at the CRU or by the CRU staff as part of this study.

Double click in the table to edit it in Excel. To add more rows, right click in the cell where you would like to add a row and select "insert row." The new rows will not auto calculate unless you copy and paste the formula from an existing row. PLEASE NOTE: Total CRC Cost and Total Other Cost do not auto calculate and must be manually entered. Please make sure that the entire table is visible – to adjust the size, place your cursor over one of the black squares around the table. Your cursor will become a double arrow that you can drag to enlarge the table. When you are done, click outside the table.

Type of Determination[1]	Site of Analysis[2]	# of Determinations Per Patient	# of Determinations Total for Study	Cost Per Test	Who Will Pay[3]	Totals*

Total CRC Cost:
Total Other Cost: $ 0.00
***Total Cost:** $0.00

* This field is auto-calculated. If the cost breakdown is different for this study, modify as necessary.

[1]e.g. CBC, Liver Profile, MRI, Nutrient Analysis, Anthropometrics, etc.

[2]e.g. Clinical Labs, Investigator's Lab, etc.

[3]e.g. Investigator's grant, patient and/or insurance, no charge, CRC, etc.

DESCRIPTION & CALCULATION - OUTPATIENT RESOURCES		AMOUNT	CARRY FORWARD IF USED
OUTPATIENT NURSING SUPPORT ***(investigator provides all supplies)***			
Pts x Visits x Hr x $ Per Hour =			$ 0.00
110	**Industry Initiated**		
65	**Other (MSSM, NIH, Foundation)**		$ 0.00
PHOTOCOPYING			
1 total patient visits X $2.00 per record			$ 2.00
OUTPATIENT USE FEE (total)			$ 0.00
OUTPATIENT USE FEE/NUMBER OF VISITS = PER VISIT CHARGE			NaN
APPLICATION & SET-UP FEE* (Industry Only)		**$1,000**	

* Application & Set-Up Fee are paid ONCE per protocol.

CRU RESOURCE UTILIZATION

DESCRIBE WHAT WILL BE PERFORMED ON THE CRU. If there are multiple locations for study visits, include a flow chart or table to delineate the procedures performed by staff in the CRU. Provide a detailed explanation of nursing services needed (i.e. physical exam, insert IV, frequency of blood draw, infuse drug, observe for X time period, etc.). If there are multiple visits with different needs, please include a Table summarizing the visits and procedures.

Signature of Principal Investigator: _____ Date:_____

ATTACHMENTS:

Please include the following as attachments to the protocol application:

A. PROTOCOL (complete NIH/Industry protocols may be submitted; otherwise, ensure that protocols include details requested in NIH applications regarding background/significance, aims/goals/hypotheses, preliminary data, research plan with detailed methodologies, statistics/power calculations, future plans, and human subjects), INVESTIGATOR'S BROCHURE (if applicable), DSMB CHARTER (if applicable)

B. ALL IRB PAPERWORK - CONSENTS, PROTOCOL SUMMARY, DSMP FORM

C. BUDGET – NOTICE OF AWARD (if applicable)

D. CRC FEE CALCULATION WORKSHEET