Submit by Email | Print Form

Irving Institute for Clinical and Translational Research
Clinical Research Center

APPLICATION FOR USE OF RESOURCES

CRC # _____ **SLR(St. Luke's-Roosevelt) #** _____
(Please leave blank; will be assigned) (Please leave blank; will be assigned)

CU IRB No. AAA _____ SLRHC IRB No. _____

NYSPI IRB No. _____

Protocol Title

Short Title

Principal Investigator: _____
Title: _____
Department/Division: _____
Mailing Address:

Contact personnel (e.g., Research Assistant, Study Coordinator)
Name: _____
Role in Study: _____
Phone: _____
E-mail: _____

Please fill out all of the sections that are relevant to your request and the Data Safety Monitoring Plan.

Are you requesting:

- ☐ Adult participant support
- ☐ Pediatric participant support
- ☐ Services of CRC Coordinator

1. In-patient days ☐ Yes ☐ No (skip to next page)

If yes, where will inpatient visits occur (e.g. HP-10, other hospital floor excluding E.D. and ICUs) _____

If yes, please provide information for the **first** year.

Approximate Number of Subjects _____

Number of admissions per subject _____

Length of longest admission (days) _____

Length of shortest admission (days) _____

Number of total days (please calculate sum of all days per patient) _____

Special nursing care:

Frequent timed blood draws (e.g. PK): ☐ **Yes** ☐ **No**

Infusion ☐ **Yes** ☐ **No**

Other (briefly describe)

2. Out-patient days ☐ **Yes** ☐ **No** **(skip to page 4, item #3)**

If yes, where will outpatient visits occur (e.g. PH-10, E.D.) _____

If yes, please provide information for the **first** year.

Approximate Number of Subjects _____

Number of visits per subject _____

Length of longest visit (hours) _____

Length of shortest visit (hours) _____

Number of total days (please calculate sum of all days per patient) _____

Additional needs:

Phlebotomy ☐ **Yes** ☐ **No**

Frequent timed blood draws (e.g. PK): ☐ **Yes** ☐ **No**

Infusion ☐ **Yes** ☐ **No**

EKG ☐ **Yes** ☐ **No**

Other (briefly describe)

3. Other CTSA Resource (e.g. Emergency Dept, ICUs) ☐ **Yes** ☐ **No** **(skip to page 4, item #3)**

If yes, please specify which Resource: _____

If yes, are you requesting the CRC Coordinator? ☐ **Yes** ☐ **No**

CRC Coordinator's Name: _____

Please list the specific duties of the CRC Coordinator (e.g. Recruitment, Data Collection)

Please provide information for the first year.

Approximate Number of Subjects _____

Number of admissions per subject _____

Length of longest admission (days) _____

Length of shortest admission (days) _____

Number of total days (please calculate sum of all days per patient) _____

Additional needs:

Phlebotomy ☐ **Yes** ☐ **No**

Frequent timed blood draws (e.g. pK): ☐ **Yes** ☐ **No**

Infusion ☐ **Yes** ☐ **No**

EKG ☐ **Yes** ☐ **No**

Other (briefly describe)

4. Bio-nutritional support: ☐ **Yes** ☐ **No** **(skip to page 6, item #5)**

Please indicate type of support for the entire study, in terms of:

Number of nutrient-controlled meals that meet protocol-specific nutrient goals per subject _____

Nutrition education materials ☐ **Yes** ☐ **No**

Number of nutrition counseling sessions per subject _____

Number of nutrient-intake monitoring assessments (food frequency questionnaires, food records etc) per subject _____

5. Biomarkers laboratory (formerly Core lab): ☐ Yes ☐ No skip to page 8, item #6)

The lab currently performs 125 different assays. These are listed on the following page (p.7).

Please place the number corresponding to the assay, followed by the approximate number of assays PER SUBJECT.

Assay Number (from next page)	Number of Assays per subject
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

If the assay is not listed, please indicate the name of the assay	Number of Assays Per subject
_____	_____
_____	_____
_____	_____

1 1,25 Dihydroxy Vitamin D
2 25 Hydroxy Vitamin D
3 3α- Androstenedione Glucuronide
4 Adiponectin
5 Adiponectin (Luminex)
6 ADMA
7 Androstenedione
8 Angiotensin
9 ANP
10 Apo A1
11 Apo B
12 APO E Genotyping
13 Aspartate
14 Asymmetric Dimethylarginine
15 BHBA
16 BNP
17 Bone Specific Alkaline Phosphatase
18 Buffy Coat Isolation / DNA Extraction
19 Camptothecin
20 cGMP
21 Cortisol
22 C-Peptide
23 CRH
24 CRP
25 Cyclophosphamide
26 Deoxypyridinoline (DPD Crosslinks)
27 Deuterated Leucine by GC/MS
28 DHEA-S
29 Direct LDL
30 Endothelin-1
31 Epigallocatechin gallate (EGCG)
32 Epinephine
33 Erythropoietin
34 e-Selectin (ELISA)
35 e-Selectin (Luminex)
36 Estradiol
37 Estrone
38 Estrone-3-Glucuronide
39 Estrone-Sulfate
40 Etoposide
41 Fatty Acids, Total
42 Folic Acid
43 Ghrenlin
44 Glucose
45 Glutamate
46 Glutathione
47 HDL / LDL Cholesterol
48 Hemoglobin A1c
49 hFSH
50 hLH
51 Homocysteine
52 ICAM (ELISA)
53 ICAM (Luminex)
54 IFN- γ (Luminex)
55 IFN- γ (ELISA)
56 IgE
57 IGF-1
58 IGFBP-3
59 IL-10 (Luminex)
60 IL-12 (Luminex)
61 IL-13 (Luminex)
62 IL-1- β (ELISA)
63 IL-1- β (Luminex)
64 IL-2 (Luminex)
65 IL-4 (Luminex)
66 IL-5 (Luminex)
67 IL-6 (ELISA)
68 IL-6 (Luminex)
69 IL-7 (Luminex)
70 IL-8 (Luminex)
71 Immunoglobulin Type E
72 Insulin
73 Insulin, HS
74 Lactate
75 Lactoferrin
76 L-Cysteine
77 Leptin
78 Leukotrine B4
79 LP(a)
80 Lysine
81 Lysine
82 Mitoxantrone
83 MMP-9
84 MMP-9 (Luminex)
85 Nerve Growth Factor-1 (NGF)
86 Neuropeptide Y
87 Norepinephrine
88 N-Telopeptide Serum (NTX-s)
89 N-Telopeptide Urinary (NTX-u)
90 Osteocalcin
91 P1NP
92 PAI-1 Active (Luminex)
93 PAI-1 Total (Luminex)
94 Palmitic Acid
95 Parathyroid Hormone (PTH)
96 Phenylalanine
97 Phosphorus
98 Pregnanediol -3a-Glucuronide
99 Progesterone
100 Proinsulin
101 Pyruvate
102 SDMA
103 Serotonin
104 Serum Calcium
105 Serum Creatinine
106 SHBG
107 Specific Gravity – Urine
108 St John's Wort
109 Suramin
110 Tamoxifen
111 Taxol
112 Taxotere
113 TNF-a (ELISA)
114 TNF-a (Luminex)
115 Topotecan
116 Total Cholesterol
117 Total Testosterone
118 Transferrin Receptors
119 Triglycerides
120 Urinary Calcium
121 Urinary Creatinine
122 Vasopressin
123 VCAM (ELISA)
124 VCAM (Luminex)
125 Vitamin B12

DATA AND SAFETY MONITORING PLAN
CLINICAL RESEARCH CENTER

STUDY TITLE (SHORT): _____

PRINCIPAL INVESTIGATOR: _____

WHAT ADVERSE EVENTS/TOXICITIES ARE EXPECTED?

IF ANY OF THESE ADVERSE EVENTS OCCUR, WHAT ACTION(S) WILL BE TAKEN?

WHO WILL BE RESPONSIBLE FOR MONITORING THIS STUDY?

IF THIS IS A CLINICAL TRIAL, WHO WILL BE MONITORING THE SAFETY DATA? WITH WHAT FREQUENCY?

LIST THE NAME(S) AND THE CONTACT INFORMATION OF THE PERSON(S) WHO MAY BE CONTACTED IN AN EMERGENCY?

PLEASE E-MAIL THE COMPLETED APPLICATION, INCLUDING ALL DOCUMENTS AND HAVE HARD COPIES DELIVERED TO:

Ms. Dianne C. Frederick, PH 10-305
Administrative Manager
dcf2111@columbia.edu

Either the original or a copy may be submitted along with copies of the following:

- **MOST RECENT** IRB Approval Letter - (if available)
- **MOST RECENT** IRB approved and stamped consent forms (if not available, please include what was submitted to the IRB)
- **MOST RECENT** Spanish consent (if applicable)
- **MOST RECENT** Protocol Data Sheet and Study Description Data Sheet from RASCAL
- DSMP (Data & Safety Monitoring Plan)
- **MOST RECENT** version of Protocol
- Investigator's Brochure (if applicable)
- Correspondence between Investigator and Sponsor documenting the role of the Investigator in the initiation and design of the study, if study is Industry-sponsored.

Please Do Not Submit Stapled or Double-sided Documents.

Your application will be sent to CRC key personnel who would be involved in your study, and to two members of the CRC Advisory Committee for a scientific review. Dianne Frederick will contact you to arrange, usually within one or two weeks, an internal review meeting (c. 30 minutes) with the CRC Program Director or Associate Program Director and staff. At this meeting, any questions or ambiguities are informally discussed.

As soon as questions, if any, from the internal review meeting, and scientific review are resolved, and the IRB approves the study, the protocol application is sent to the CRC Advisory Committee. The Committee meets once a month. A formal letter from Dianne Frederick will be sent to the study's Principal Investigator, notifying them when the protocol is approved, and they are able to begin using CRC resources. No research subjects may be scheduled until this letter has been issued.

The CRC number that will be assigned to your study will not change from year to year. The IRB numbers may, however, and you may also wish to amend the study in the future. Please inform Dianne Frederick of any changes in consent forms, IRB numbers or other revisions in the protocol.

Funding for the NIH program grant that supports the CRC depends upon continued demonstration that outstanding research is being conducted, and published, using CRC services and facilities. Therefore, **we ask that you cite the CRC grant -** 1 UL1 RR024156-03-- **on any publications related to this protocol**. We may also ask you for your grant support, biographical sketch, publications, or other information required for NIH reports and applications. We thank you in advance for your help.