**CTRC Utilization Form**

**Protocol Full Title:** Title

 **IRB #:**  ##-####

**Version Date:**  Version date

# Summary of Study Personnel

**1.1 Principal Investigator**

|  |  |
| --- | --- |
| Name: First MI Last | Degree: Degree |
| Department: Department | PI Title: PI’s Title |
| ERA-Commons (Required): ERA-Commons | Phone: ###-###-####. |
| Email: EmailAddress@colorado.edu | Campus Box: ### |

Are you a CCTSI member? \_\_\_\_

[CCTSI membership is required: <https://cctsi.cuanschutz.edu/funding/membership>]

**1.2 \*Information for Primary Contact Person If Other Than PI**

|  |  |
| --- | --- |
| Study Coordinator: First MI Last | Degree: Degree |
| Department: Department | Phone: ###-###-####. |
| Email: EmailAddress@colorado.edu | Campus Box: ### |
| ERA-Commons (Required): ERA-Commons |  |

**1.3 Co- Investigators:**

|  |  |  |
| --- | --- | --- |
| **First Name, Last Name, Degree** | **ERA-commons Name REQUIRED** | **Email Address** |
| First MI Last, Degree | ERA-Commons | EmailAddress@colorado.edu |
| First MI Last, Degree | ERA-Commons | EmailAddress@colorado.edu |
| First MI Last, Degree | ERA-Commons | EmailAddress@colorado.edu |
| First MI Last, Degree | ERA-Commons | EmailAddress@colorado.edu |
| First MI Last, Degree | ERA-Commons | EmailAddress@colorado.edu |

# Protocol Attributes

**2.1 Study Information**

Proposed Study Subject Category:

[ ]  Investigator initiated RESEACH purposes only

[ ]  Investigator initiated study and includes a non-research patient care component

[ ]  Industry initiated study

[ ]  Pilot study to determine feasibility/acceptability for future research.

Has immediate submission of this protocol been mandated by the funding agency**?** [ ] Yes [ ] No

Has the protocol or grant been peer-reviewed by an independent body (such as NIH study section or the FDA)?[ ] Yes [ ] No

If Yes, name of the independent body.

Has the protocol changed since it was reviewed by that independent body?[ ] Yes [ ] No

Is this study AIDS/HIV related?[ ] Yes [ ] No

Is this a clinical trial? [ ] Yes [ ] No

If so, please indicate phase:\_\_\_\_\_\_

Clinical Trial: Phase NCT: Please enter NA if not applicable.

Is this a multi-site study? [ ] Yes [ ] No

Are the other sites local? [ ] Yes [ ] No

Multiple national or international sites? [ ] Yes [ ] No

 If a multi-site study, list other sites and primary site.

**2.2 External Funding Information:**

Is this study funded in part (or total) by peer reviewed grant funds? [ ] Yes [ ] No

|  |  |
| --- | --- |
| Funding Agency:\_\_\_\_\_\_\_\_\_ | Grant number: \_\_\_\_\_\_\_\_\_ |
| Speedtype: \_\_\_\_\_\_\_\_\_ | Type of Award: \_\_\_\_\_\_\_\_\_ |

Is this study funded in part (or in total) by industry funds? [ ] Yes [ ] No

If yes, what/who is the sponsoring entity? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| Speedtype: \_\_\_\_\_\_\_\_\_ | Grant number: \_\_\_\_\_\_\_\_\_ |

**2.2 Alternate Funding Information:**

If your study has no external funding, how do you plan to pay for costs over what the CTRC can support?

 (Please describe your funding.)

**2.2 Subject Characteristics**

Which subject populations will you recruit? **(***Check all that apply)*

[ ]  **Healthy Volunteers** [ ]  **Subjects with specific conditions**

[ ]  **Pregnant Women** [ ]  **Neonates**

[ ]  **Prisoners** [ ]  **Decisionally Challenged**

[ ]  **Non-English Speakers** [ ]  **N/A**

Have you successfully enrolled similar populations in previous studies? [ ] Yes [ ] No

Do you foresee any major barriers to recruitment? [ ] Yes [ ] No

If yes, Identify and explain how you will overcome these barriers.

What are the ages of the subjects? (Check all that apply)

 [ ]  < 30 days

 [ ]  > 30 days and < 1 year

 [ ]  > 1 year and < 18 years

 [ ]  18 years to 64 years

 [ ]  > 65 years

**2.3 Recruitment Plan:**

Estimated Accrual Duration (months):Number of months the protocol will be accepting accruals

Local Protocol Enrollment (on study): Expected number of subjects to accrue locally

If Multi-center Study: Expected number of subjects to accrue for entire study and sites

Total Anticipated Duration of Study (months): Expected number of months to study completion

**2.4 Outpatient Visits:**

Expected number of CTRC visits per subject: \_\_\_\_\_\_\_\_\_

Estimated cumulative duration of CTRC visits (in hours): \_\_\_\_\_\_\_\_\_

*For assistance with budgeting and costs of requested services, please contact Nikki Leonardo*

*CTRC Administrative Manager,* *Leonardo@colorado.edu****303-735-2521.***

Summary of Requested Nursing Services

**3.1 Outpatient Nursing Services:**

*Contact the CTRC Nursing Team with questions:* *CTRCNurse@colorado.edu* *or 303-735-2304*

Please check all services requested:

|  |  |
| --- | --- |
| **Requested Services** | **What visits will these be needed** |
| [ ] Arterial catheterization & monitoring  | #, #, #, #, #, #, |
| [ ] Arterial Pharmacological Infusion  | #, #, #, #, #, #, |
| [ ] Blood Pressure monitoring / screening  | #, #, #, #, #, #, |
| [ ] Cardio vascular monitoring | #, #, #, #, #, #, |
| [ ] Check in Visits  | #, #, #, #, #, #, |
| [ ] Electrocardiogram  | #, #, #, #, #, #, |
| [ ] Endothelial cell harvesting  | #, #, #, #, #, #, |
| [ ] Fat Biopsy  | #, #, #, #, #, #, |
| [ ] History and Physical  | #, #, #, #, #, #, |
| [ ] Intravenous Glucose Tolerance Testing | #, #, #, #, #, #, |
| [ ] Muscle biopsy | #, #, #, #, #, #, |
| [ ] Oral Glucose Tolerance Testing | #, #, #, #, #, #, |
| [ ] Oral meds administration  | #, #, #, #, #, #, |
| [ ] Phlebotomy  | #, #, #, #, #, #, |
| [ ] Venous catheterization | #, #, #, #, #, #, |
| [ ] Venous Pharmacological Infusion | #, #, #, #, #, #, |
|  |  |
| [ ] Other: \_\_\_\_\_\_\_\_\_ | #, #, #, #, #, #, |

**3.2 Integrative Physiology Core Lab (IPCL) Services:**

*Contact the IPCL manager with questions: Albert.Angiolillo@colorado.edu, 303-735-1377 UCB*

|  |  |
| --- | --- |
| **Requested Services** | **What visits will these be needed** |
| [ ] Activity Question  | #, #, #, #, #, #, |
| [ ] Ankle Brachial Index  | #, #, #, #, #, #, |
| [ ] DEXA Scan  | #, #, #, #, #, #, |
| [ ] Graded Exercise Testing  | #, #, #, #, #, #, |
| [ ] Resting metabolic rate  | #, #, #, #, #, #, |
| [ ] Skin Folds  | #, #, #, #, #, #, |
| [ ] VO2 Max  | #, #, #, #, #, #, |
| [ ] Waist to Hip Ratio | #, #, #, #, #, #, |
|  |  |
| [ ] Other: \_\_\_\_\_\_\_\_\_ | #, #, #, #, #, #, |

**3.2 Pharmacy Support Services:**

|  |  |
| --- | --- |
| **Requested Services** | **What visits will these be needed** |
| [ ] Blind Study Randomization  |  |
| [ ] Oral Study Medication  | #, #, #, #, #, #, |
| [ ] Pharmacological Infusion  | #, #, #, #, #, #, |
|  |  |
| [ ] Other: \_\_\_\_\_\_\_\_\_ | #, #, #, #, #, #, |

Summary of Requested Laboratory Tests and Analyses

*Please visit our website for Laboratory and Pricing information:*

[*https://www.colorado.edu/ctrc/investigators/specimen-processing-and-pricing*](https://www.colorado.edu/ctrc/investigators/specimen-processing-and-pricing)

**4.1 CTRC in house services:**

Female HCG Screen [ ] Initial screening [ ]  Additional Visits: \_\_\_\_\_\_

Tox Screen [ ] Initial screening [ ]  Additional Visits: \_\_\_\_\_\_

Other Urine Collection [ ]  Visits: \_\_\_\_\_\_

**4.2 Requested Lab Assays:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Lab** | **Test** | **Visits** | **Tube Specifications** |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |
| *Lab* | Test | #, #, #, #, #, #, | \*PI tests: tube type & size |

Summary of Requested Nutrition Services (Available at UCB site)

*\*****Important Note****: Prior to submitting your application, if Nutrition support is required you must discuss your needs and confirm availability with contact Kathleen Farrell at the Boulder CTRC:* ***Kathleen.Farrell@Colorado.Edu****,* ***303-735-2125****. If requesting Denver CTRC support, please contact Dr. Janine Higgins as well at:* ***Janine******Higgins@ChildrensColorado.Edu****,* ***720-777-2955****.*

**5.1 Does your protocol require Nutrition support?** [ ] Yes [ ] No (skip to next section)

**5.2 If yes, please answer the following:**

***Check ALL that apply; if no category is checked, no Nutrition services will be provided for this protocol:***

[ ] Non-controlled snack or post meal ***- e.g.,*** ***snack following exercise test or RMR (< 2 hours for testing session)*** and ***post meal following an experimental session (> 4 hours experimental session), must complete section*** **5A**)

[ ] Nutrient controlled research diet (must complete section **5A**)

[ ]  Nutrient intake analysis (e.g., diet records or food frequency questionnaire (FFQ), must complete section **5B**)

[ ]  Nutrition assessment, instruction or education (must complete section **5C**)

[ ] Other. Please specify: \_\_\_\_\_\_\_\_\_

**5.3A. If you are requesting the provision of ANY foods or beverages, please answer the following:**

|  |  |  |  |
| --- | --- | --- | --- |
| Are any ***outpatient SNACKS*** to be served? | [ ] Yes | [ ] No | If yes, which visits? \_\_\_\_\_\_ |
| Are any ***outpatient POST MEALS*** to be served? | [ ] Yes | [ ] No | If yes, which visits? \_\_\_\_\_\_ |
| Will a ***CALORIE CONTROLLED RESEARCH DIET*** be used? | [ ] Yes | [ ] No |  |
| ***If yes****, what is the purpose of providing a* ***RESEARCH DIET****?* | \_\_\_\_\_\_ |
| *How will the target calorie level for each participant be calculated?* | \_\_\_\_\_\_ |
| Which of the following nutrients will be controlled in the diet: ***Check ALL that apply*** |
| [ ]  CHO - Specify amount / ratio \_\_\_\_\_\_ | [ ]  Sodium - Specify amount / ratio \_\_\_\_\_\_ |
| [ ]  Fat - Specify amount / ratio \_\_\_\_\_\_ | [ ]  Fatty Acid Subtype – Specify amount / ratio \_\_\_\_\_\_ |
| [ ]  Protein – Specify amount / ratio \_\_\_\_\_\_ | [ ]  w-6 Fatty Acids – Specify amount / ratio \_\_\_\_\_\_ |
| [ ]  Fiber - Specify amount / ratio \_\_\_\_\_\_ | [ ]  w-3 Fatty Acids – Specify amount / ratio \_\_\_\_\_\_ |
| [ ]  Sugar - Specify amount / ratio \_\_\_\_\_\_ | [ ]  Micronutrients – Name & Specify amount / ratio \_\_\_\_\_\_ |
| [ ]  Complex CHO/Simple Sugar - Specify amount / ratio \_\_\_\_\_\_ | [ ]  Micronutrients – Name & Specify amount / ratio \_\_\_\_\_\_ |
| [ ]  Cholesterol – Specify amount / ratio \_\_\_\_\_\_ | [ ]  Other \_\_\_\_\_\_ |

**5.3B. If you are requesting nutrient intake analysis, please answer the following:**

|  |  |
| --- | --- |
| What specific dietary parameters would you like to assess? (e.g. kcal, protein, habitual macronutrient intake, etc.) | \_\_\_\_\_\_ |
| At what time points would you like diet assessed? | \_\_\_\_\_\_ |
| Which method of intake reporting will be used? | [ ]  3 or 4 Day Diet Record [ ]  Food Frequency Questionnaire (FFQ) [ ]  24 Hour Diet Recall [ ]  Other Specify: \_\_\_\_\_\_ |

**5.3C. If you are requesting a nutrition assessment questionnaire, instruction or education, please answer the following:**

|  |  |
| --- | --- |
| Would like to have your subjects fill out a nutrition assessment questionnaire (NAQ) using REDCAP to screen for supplements, dietary intolerances, etc.? | [ ] Yes [ ] No **If yes**, Nutrition department has a standard questionnaire, however, if you would like the NAQ to be tailored to meet your study’s dietary needs please specify. \_\_\_\_\_\_ |
| What is the goal of the counseling session? (e.g., weight loss, low sodium, etc.) | \_\_\_\_\_\_ |
| At what time points will counseling be provided? | \_\_\_\_\_\_ |
| How long will each counseling session last? | \_\_\_\_\_\_ |
| Will you be providing core materials for counseling sessions? | [ ] Yes [ ] No  **If no**, please explain what materials will be required \_\_\_\_\_\_ |
| Are the core materials obtained from/based on guidelines from a professional or government organization (e.g., ADA, Obesity Society, USDA, NIH)? | [ ] Yes [ ] No  **If yes**, please name the organization and source of the materials \_\_\_\_\_\_ |

Summary of Requested Biostatistics Services

*Contact the CTRC biostatistician for assistance:* *Eric.Vance@colorado.edu*

**6.1 Which of the followin Biostatistic Services did you or will you utilize?**

[ ]  Study design support

[ ]  Sampling plan support

[ ]  Sample size calculations

[ ]  Analytical support

[ ]  Software tool selection/training

[ ]  Report, publication, presentation, conference preparation

[ ]  Other: \_\_\_\_\_\_

Did you consult the CTRC Biostatistician during the design of your research protocol? [ ] Yes [ ] No

Summary of Requested Research Subject Advocate Services

*Contact the CTRC RSA or assistance:* *Tanya.Alderete@colorado.edu*

**7.1 Which of the following RSA services did you or will you utilize?**

[ ]  Human subjects risks, study alternatives, protections and mitigation support

 [ ]  Data safety monitoring plan development

 [ ]  Development of the informed consent document

 [ ]  Establishment of a data safety and monitoring board or safety officer

 [ ]  Serious adverse events (SAE) definitions, procedures, assistance

 [ ]  HIPAA compliance

[ ]  Ethical, legal and social implications (ELSI) associated with this study

[ ]  Standard Operating Procedures for GCP

[ ]  Data Safety Monitoring Board or Safety Officer Charter templates

[x]  Other: \_\_\_\_\_\_