**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*](mailto: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*](mailto: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:* [*Jared.Greiner@colorado.edu*](mailto:Jared.Greiner@colorado.edu)

|  |  |
| --- | --- |
| **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://cctsi.cuanschutz.edu/resources/ctrc/pricing" \l "ac-ctrc-core-lab-assays-and-pricing-3)*

**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***](mailto: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*](mailto: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:* [*Monika.Fleshner@colorado.edu*](mailto:Monika.Fleshner@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

Other: \_\_\_\_\_\_