

Study Details

Study hypotheses
(Maximum 70 words):

List study specific aims
(Maximum 115 words):

Brief protocol summary
(Maximum 185 words, include major aspects of study design and primary endpoints):

Recruitment Plan and Enrollment Details

Recruitment Strategies (select multiple)

Please briefly describe justification for recruitment strategies

Total projected enrollment:

Recruitment Period (in months)

Study Duration (in years)

Study subject enrollment by site

Select Site

Outpatient

Total # of Outpatient Visits Per Subject

Approximate length of outpatient visit (in hours/minutes)

Total Projected # of Subjects at this site

Inpatient

Total # of Inpatient Visits Per Subject

Total # of Inpatient Days Per Visit

Select Site

Outpatient

Total # of Outpatient Visits Per Subject

Approximate length of outpatient visit (in hours/minutes)

Total Projected # of Subjects at this site

Inpatient

Total # of Inpatient Visits Per Subject

Total # of Inpatient Days Per Visit

Select Site

Outpatient

Total # of Outpatient Visits Per Subject

Approximate length of outpatient visit (in hours/minutes)

Total Projected # of Subjects at this site

Inpatient

Total # of Inpatient Visits Per Subject

Total # of Inpatient Days Per Visit

CRN Resources Requested

- Nursing Services If checked, complete Nursing section below
- Core Lab Services If checked, complete Core Lab section below, lab staff will contact you for additional details as needed
- Bionutrition/Exercise Physiology Services If checked, complete Bionutrition/Exercise Physiology section below
- Clinical Data Extraction Services To get started, contact Jeff Weaver at jeff.weaver@emory.edu
- Other Please Describe:

Nursing Services

Nursing Services Requested (select multiple):

Additional Details:

Specific equipment needed or provided:

Core Lab Services

Basic Laboratory Processing

Specimen Type

Blood Urine Saliva Stool

Other Please describe:

Genomic Processing Service

RNA DNA

Point of Care Testing

Pregnancy test Glucose Drug Screen

Storage and Specimen Routing Services

Short Term Freezer Storage (≤ 6 months) Specimen Routing to non-CRN sites

Long Term Freezer Storage Study set-up (e.g. collection kits)

After Hour Processing (5:00pm - 7:00am)

Sample Requirements - SECTION TO BE COMPLETED BY LAB STAFF

Type of Sample

Lavender	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
Heparin	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
SST	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
Red Top	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
Blue	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
Gold	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
PAX-DNA	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
Tempus	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
Urine	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
Others	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>
Special Handling	<input type="text"/>	Number Samples:	<input type="text"/>	Number Aliquots:	<input type="text"/>	Number Visits:	<input type="text"/>

Special Handling
Details:

Bionutrition & Exercise Physiology Services

Body Composition

Indirect Calorimetry	<input type="text"/>
Bioelectrical Impedance Analysis	<input type="text"/>
Skin fold measurements	<input type="text"/>
Anthropometric measurements	<input type="text"/>
DEXA	<input type="text"/>

Food Record Analysis

24-hr Food recall collection and analysis	<input type="text"/>
Food record documentation and analysis	<input type="text"/>
Food Frequency Questionnaire	<input type="text"/>
<input type="checkbox"/> Willett	<input type="checkbox"/> Block

Meals/Snacks

Type of diet:

Prepared by Metabolic Kitchen

Prepared by Main Hospital Kitchen

Other needs/requests:

Exercise Testing

Submax	<input type="text"/>
VO2 max	<input type="text"/>

Cardiovascular Testing

FMD?	<input type="text"/>
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Education & Counseling

Type of diet:

Exercise prescription

Group sessions

Individual sessions

IRB Approvals

IRB of Record (check one)

- Emory University
- Georgia Institute of Technology
- Morehouse School of Medicine
- Children's Healthcare of Atlanta
- Atlanta VAMC
- Western IRB
- UGA

IRB Status

IRB #

IRB Approval Date

Funding and Regulatory Information

Sponsor/Funding Agency Name:

Grant/Contract Number:

Award/Contract Dates:

Investigator Initiated?

Study Type

Clinical Trial Phase

HIV/AIDS related protocol?

Pediatrics related protocol?

Is there an IND/IDE associated with this protocol?

If yes, please complete the following

IND/IDE number(s):

IND/IDE Sponsor(s):

Submission Checklist - Please ensure form is complete. Forward this application along with the following documents to:

CRN@emory.edu

- Protocol/Research Plan
- NIH style biosketch for PI and all co-investigators
- DSMP (Template found on ACTSI website - link below)
- Day to day orders (Template found on ACTSI website-link below)
- IRB Approval Letter IRB Approval pending
- Informed Consent Documents

For more information, go to the [ACTSI website](#) or email CRN@emory.edu.