

Department of Nutrition Science

**Purdue University - Clinical Research Center (PU-CRC): Protocol Review**

**Protocol Information:**

Protocol Title	
IU Protocol #/Purdue CRC Protocol #	
Funding Source (name) <i>IF NIH, include funding agency and #</i>	
Status (select one)	Submitted    Pending    Funded
Funding Dates	
Review (select one)	Original Protocol    Amendment* <i>*if this is an amendment, please highlight only the items that are revised</i>
IRB #	
Status (select one)	Pending    or    Approved (date of approval:    )
Primary Investigator Department Email/Phone	
Co-Investigators Department	
Primary Contact Email/Phone	

**Experimental Design Information:**

Estimated Start Date/End Date	
# of Participants	to Screen:                                  to Complete: to Enroll:    on Active Protocol (at one time):
Participant Duration (# days)	
Design	Cross-over    Randomized Controlled Trial    Observational    Parallel    Other
Diet Design (select all that apply)	Full-feed    Partial-feed    Preload/Single Meal    Supplement
# of Interventions	
Visits (#/participant)	# Study Clinical Visits:                  # Study Meal Pickup Visits:                  # TOTAL visits:
Enrollment type (circle one)	Rolling (# of waves:    )    or    All enrolled before intervention
Location (circle all that <i>may</i> apply)	Stone Hall: 124A (Conference/dining)    124D-J (Taste-test/Meal Consumption) 144A-B (Conference/dining)    151 152 (Phlebotomy Chairs)    149 (Hospital Bed) G92 (Hospital Beds)    147 (Exercise Facility) Lyles Porter: 1144C (Phlebotomy Chairs)    1144F (Hospital Beds) 1145-1148 (Consult Rooms)    1107 (Demo-Kitchen) 1151 (Taste/Sensory Lab) Other:

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**PU-CRC: SUMMARY**

Please  the items you want to utilize (regardless of whether you are requesting assistance or not.)

<p style="text-align: center;"><u>Administrative Assistance</u></p> <input type="checkbox"/> IRB submission <input type="checkbox"/> Recruitment <input type="checkbox"/> Diet Development (for protocol) <input type="checkbox"/> Protocol Consultation	<p style="text-align: center;"><u>Visit Space</u></p> <input type="checkbox"/> Interview/Counseling <input type="checkbox"/> Bed <input type="checkbox"/> Chair (for blood-collection) <input type="checkbox"/> Chair (taste/meal consumption)	<p style="text-align: center;"><u>Bone Imaging</u></p> <input type="checkbox"/> DXA <input type="checkbox"/> pQCT <input type="checkbox"/> MicroCT
<p style="text-align: center;"><u>Nutrition Services</u></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> Full-feeding Diet Development           <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized (per group)</li> <li><input type="checkbox"/> Other: _____</li> </ul> <input type="checkbox"/> Partial-feeding Diet Development           <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized (per group)</li> <li><input type="checkbox"/> Other: _____</li> </ul> <input type="checkbox"/> Single-meal Development           <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized (per group)</li> <li><input type="checkbox"/> Other: _____</li> </ul> </div> <div style="width: 45%;"> <input type="checkbox"/> Full-feeding Diet Prep/Pack-out  <input type="checkbox"/> Partial-feeding Diet Prep/Pack-out  <input type="checkbox"/> Single-meal Prep/Pack-out  <input type="checkbox"/> Single-meal Delivery  <input type="checkbox"/> Diet Record/Recall Collection  <input type="checkbox"/> Diet Record/Recall Analysis  <input type="checkbox"/> Nutritional Counseling  <input type="checkbox"/> Weigh Backs           </div> </div>		<p style="text-align: center;"><u>Body Composition</u></p> <input type="checkbox"/> DXA <input type="checkbox"/> Anthropometrics <ul style="list-style-type: none"> <li><input type="checkbox"/> Weight</li> <li><input type="checkbox"/> Height</li> <li><input type="checkbox"/> Waist Circumference</li> <li><input type="checkbox"/> Waist to Hip</li> <li><input type="checkbox"/> Other: _____</li> </ul> <input type="checkbox"/> BOD-POD <input type="checkbox"/> Skinfolds (Caliper) <input type="checkbox"/> Other: _____
<p style="text-align: center;"><u>Other Clinical Measures</u></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> Single-stick (butterfly needle) with Blood Sample Collection and Processing  <input type="checkbox"/> IV Catheter Placement  <input type="checkbox"/> Blood Sample Collection (from catheter, with processing)  <input type="checkbox"/> Blood Sample Collection (from catheter, no processing)  <input type="checkbox"/> Other: _____           </div> <div style="width: 45%;"> <input type="checkbox"/> Continuous Glucose Monitor (CGMS) Insertion  <input type="checkbox"/> Blood Pressure  <input type="checkbox"/> Urine Sample Collection  <input type="checkbox"/> Pregnancy Test  <input type="checkbox"/> Accelerometry/Actigraphy           </div> </div>		<p style="text-align: center;"><u>Specimen Processing</u></p> <input type="checkbox"/> Initial Processing <input type="checkbox"/> Short-term Storage <input type="checkbox"/> Send Out Samples <input type="checkbox"/> Other: _____

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**Additional Information IF Requesting Bionutrition Services:**

<b>Full-Feeding Cost Estimates</b>	<b>PU-CRC only</b>
<p><input type="checkbox"/> Full-feeding Diet Development</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized (per group/per intervention)</li> <li><input type="checkbox"/> Other: _____</li> </ul> <p>Describe: _____</p> <p>Select which eating occasions to be <b><i>developed</i></b>:</p> <p><input type="checkbox"/> Breakfast   <input type="checkbox"/> Lunch   <input type="checkbox"/> Dinner   <input type="checkbox"/> Mid-morning Snack   <input type="checkbox"/> Mid-afternoon Snack</p> <p>____ # subjects/group   ____ # groups   ____ # days/menu   ____ # interventions</p> <p><input type="checkbox"/> Full-feeding Diet Preparation/Pack-out</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized (per group)</li> <li><input type="checkbox"/> Other: _____</li> </ul> <p>Describe: _____</p> <p>Select which eating occasions to be <b><i>prepared/packed-out</i></b>:</p> <p><input type="checkbox"/> Breakfast   <input type="checkbox"/> Lunch   <input type="checkbox"/> Dinner   <input type="checkbox"/> Mid-morning Snack   <input type="checkbox"/> Mid-afternoon Snack</p> <p>____ # subjects/group   ____ # groups   ____ # interventions   ____ # days/intervention</p> <p>____ # total breakfasts   ____ # total lunches   ____ # total dinners</p> <p>____ # total mid-morning snacks   ____ # total mid-afternoon snacks</p> <p><input type="checkbox"/> Weigh Backs</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Every Meal/Snack   <input type="checkbox"/> Every Test Day Meal/Snack   <input type="checkbox"/> Indiv. Meal/Snack Components</li> </ul> <p>____ # subjects x ____ # days x ____ # eating occasions x ____ # study time pts</p> <p><input type="checkbox"/> Grocery Shopping   ____ # total study weeks/subject</p> <p><input type="checkbox"/> Delivery</p>	<p>Cost Estimate: <u>cost x # subjects x # time pts</u></p>

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**Additional Information IF Requesting Bionutrition Services:**

Partial-Feeding Cost Estimates	PU-CRC only
<p><input type="checkbox"/> Partial-feeding Diet Development</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized (per group/per intervention)</li> <li><input type="checkbox"/> Other: _____</li> </ul> <p>Describe: _____</p> <p>Select which eating occasions to be <b><u>developed</u></b>:</p> <p><input type="checkbox"/> Breakfast   <input type="checkbox"/> Lunch   <input type="checkbox"/> Dinner   <input type="checkbox"/> Mid-morning Snack   <input type="checkbox"/> Mid-afternoon Snack</p> <p>____ # subjects/group   ____ # groups   ____ # days/menu   ____ # interventions</p> <p><input type="checkbox"/> Partial-feeding Diet Preparation/Pack-out</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized (per group/per intervention)</li> <li><input type="checkbox"/> Other: _____</li> </ul> <p>Describe: _____</p> <p>Select which eating occasions to be <b><u>prepared/packed-out</u></b>:</p> <p><input type="checkbox"/> Breakfast   <input type="checkbox"/> Lunch   <input type="checkbox"/> Dinner   <input type="checkbox"/> Mid-morning Snack   <input type="checkbox"/> Mid-afternoon Snack</p> <p>____ # subjects/group   ____ # groups   ____ # interventions   ____ # days/intervention</p> <p>____ # total breakfasts   ____ # total lunches   ____ # total dinners</p> <p>____ # total mid-morning snacks   ____ # total mid-afternoon snacks</p> <p><input type="checkbox"/> Weigh Backs</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Every Meal/Snack   <input type="checkbox"/> Every Test Day Meal/Snack   <input type="checkbox"/> Indiv. Meal/Snack Components</li> </ul> <p>____ # subjects x ____ # days x ____ # eating occasions x ____ # study time pts</p> <p><input type="checkbox"/> Grocery Shopping   ____ # study weeks</p> <p><input type="checkbox"/> Delivery</p>	<p><b>Cost Estimate:</b> cost x # subjects x # time pts</p>

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**Additional Information IF Requesting Bionutrition Services:**

Single-Feeding Cost Estimates	PU-CRC only
<p><input type="checkbox"/> Single-meal Development</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized           <ul style="list-style-type: none"> <li><input type="checkbox"/> per group</li> <li><input type="checkbox"/> all subjects</li> </ul> </li> <li><input type="checkbox"/> Other: _____ Describe:</li> </ul> <p>Select which eating occasions to be <b><i>developed</i></b>:</p> <p><input type="checkbox"/> Breakfast   <input type="checkbox"/> Lunch   <input type="checkbox"/> Dinner   <input type="checkbox"/> Mid-morning Snack   <input type="checkbox"/> Mid-afternoon Snack</p> <p>___ # subjects/group   ___ # groups   ___ # interventions</p> <p><input type="checkbox"/> Single-meal Preparation/Packout</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Tightly-controlled (weighed)</li> <li><input type="checkbox"/> Individualized (per subject)</li> <li><input type="checkbox"/> Pre-set/standardized           <ul style="list-style-type: none"> <li><input type="checkbox"/> per group</li> <li><input type="checkbox"/> all subjects</li> </ul> </li> <li><input type="checkbox"/> Other: _____ Describe:</li> </ul> <p>Select which eating occasions to be <b><i>prepared/packed-out</i></b>:</p> <p><input type="checkbox"/> Breakfast   <input type="checkbox"/> Lunch   <input type="checkbox"/> Dinner   <input type="checkbox"/> Mid-morning Snack   <input type="checkbox"/> Mid-afternoon Snack</p> <p>___ # subjects/group   ___ # groups   ___ # interventions   ___ # days/intervention</p> <p>    ___ # total breakfasts   ___ # total lunches   ___ # total dinners</p> <p>    ___ # total mid-morning snacks   ___ # total mid-afternoon snacks</p> <p><input type="checkbox"/> Single-meal Delivery                                      ___ # subjects x ___ # days</p> <p><input type="checkbox"/> Weigh Backs</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Every Meal/Snack   <input type="checkbox"/> Every Test Day Meal/Snack   <input type="checkbox"/> Indiv. Meal/Snack Components</li> </ul> <p>    ___ # subjects x ___ # days x ___ # eating occasions x ___ # study time pts</p> <p><input type="checkbox"/> Grocery Shopping   ___ # study weeks</p>	<p>Cost Estimate: <u>cost x # subjects x # time pts</u></p>

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**Additional Information IF Requesting Bionutrition Services:**

<b>Dietary Assessment &amp; Other Costs</b>	<b>PU-CRC only</b>
<p><input type="checkbox"/> Diet Record/Recall (in person) &amp; Analysis                  ___# subjects x ___# days x ___# study time pts</p> <p><input type="checkbox"/> Diet Recall (in real time, phone) Analysis                  ___# subjects x ___# days x ___# study time pts</p> <p><input type="checkbox"/> Diet Record/Recall Analysis                  ___# subjects x ___# days x ___# study time pts</p> <p><input type="checkbox"/> Nutritional Counseling                  ___# subjects x ___# days x ___# study time pts</p> <p><input type="checkbox"/> Student Services (taste-testing/additional prep)                  Describe:</p> <p><input type="checkbox"/> Other:</p>	<p>Cost Estimate:  <u>cost x # subjects x # time pts</u></p>

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**Additional information IF requesting clinical use &/or clinical manager services**

Clinical Use &/or Services	PU-CRC only
<p> <input type="checkbox"/> DXA      <input type="checkbox"/> Clinical Manager Needed  <input type="checkbox"/> pQCT      <input type="checkbox"/> Clinical Manager Needed  <input type="checkbox"/> MicroCT   <input type="checkbox"/> Clinical Manager Needed  <input type="checkbox"/> Anthropometrics   <input type="checkbox"/> Clinical Manager Needed              <input type="checkbox"/> Weight              <input type="checkbox"/> Height              <input type="checkbox"/> Waist Circumference              <input type="checkbox"/> Waist to Hip              <input type="checkbox"/> Other: _____  <input type="checkbox"/> BOD-POD   <input type="checkbox"/> Clinical Manager Needed  <input type="checkbox"/> Skinfolds (Caliper)   <input type="checkbox"/> Clinical Manager Needed  <input type="checkbox"/> IV Placement with Clinical Manager              <input type="checkbox"/> Weekends   <input type="checkbox"/> Weekdays   ~time of day: _____  <input type="checkbox"/> Blood sample collections from IV Catheter by Clinical Manager              _____ # samples _____ time intervals (min)  <input type="checkbox"/> Single-stick with Blood Sample Collection with Clinical Manger              <input type="checkbox"/> Weekends   <input type="checkbox"/> Weekdays   ~time of day: _____                  <input type="checkbox"/> Blood Processing by Clinical Manager                  <input type="checkbox"/> Send Out Sample by Clinical Manager  <input type="checkbox"/> Urine Sample Collection by Clinical Manager  <input type="checkbox"/> CGMS Insertion/Removal by Clinical Manager  <input type="checkbox"/> Blood Pressure by Clinical Manager  <input type="checkbox"/> Pregnancy Test by Clinical Manager  <input type="checkbox"/> Accelerometry/Actigraphy by Clinical Manager  <input type="checkbox"/> Other by Clinical Manager: _____         </p>	<p>Cost Estimate: <u>cost x # subjects x # time pts</u></p>

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Summary: (To be completed by CRC Oversight Committee)

Date of Review:

Estimated BioNutrition Costs	
Estimated Clinical Costs	
CRC Review Determination	Approve Request Revisions* Additional Discussions Needed
Estimated Start Date (based on BioNutrition Services)	
Estimated Start Date (based on Clinical Services)	

\*Request Revision Comments:

Once the Oversight Committee has reviewed and provided feedback, please sign below acknowledging the costs and review:

PI: \_\_\_\_\_

Date: \_\_\_\_\_

CRC Oversight Committee:

Faculty: Regan Bailey

CRC Staff: Amy Wright      Robin Rhine      Lana Merrick      Anne Wilcox

CRC Director: Michele Forman