

Boston Children's Hospital /Framingham State University

Diet Study Grant—Program Needs

Description of Grant (10/1/13 – 6/30/16)

The University is partnering with Boston Children's Hospital (BCH) in a nutrition and weight loss study to be conducted on campus investigating the question, "Is a calorie just a calorie?" The \$12 M grant, funded by the newly formed Nutrition Science Initiative (NuSI) will provide \$3+M to the University.

In summary, 75 students, faculty or staff at the University (a total of 150 participants over two years: AY 14-15 and 15-16) will participate in a period of weight reduction, followed by randomization into three different diets: high carbohydrate, moderate-carbohydrate and low-carbohydrate to analyze the impact of energy expenditure during weight loss maintenance. Participants will receive a stipend for their participation. Sodexo will prepare the food and provide separate access cafeteria and delivery service for the participants.

I. Space Requirements

Study Home (to begin asap)

This space will be used to provide a campus home for the study. Researchers will provide their own laptops.

- 4 Desks and 4 office chairs
- 2 computers, monitors
- Basic office small equipment (such as stapler, paper, paper clips, tape dispenser, etc.)
- Wireless access
- Electrical outlets (for the laptops)
- 4 phone connections
- Copy machine/access—since we will not have copy machine access we will need to purchase a printer/copier combination for spring semester. This will allow for consent forms to be copied so that each participant leaves with a copy of the form.

Once the move to O'Connor is made an additional office space for the home office will be required. We suggest O'Connor G29.

Recruitment Phase (to begin 3/10/14 through 5/2/14* and again 2/1/15 through 5/15)

This space will be used to conduct informational sessions and screening sessions. It would be ideal to combine or be close to the Study Home space.

*The Tax House space will be used for this period of time. Once we move to O'Connor we will need the use of one additional office in the same area as highlighted below.

Submitted to Dr. Dale Hamel, Dr. Linda Vaden-Goad, Dr. Susanne Conley, Warren Fairbanks by Dr. Pat Luoto, Project Director

CC: Maureen Fowler

- General, secured office space and secure file cabinets. BCH will purchase a hasp lock for the office space.
- Meeting space to review study details with participants, recruitment requirements, screening consent. Some of this can be done in small group settings, but private areas for questions and signed consent will be required. The private areas could be created with privacy screens.
- Initial assessments
- Private area to weigh and measure participants
- Equipment space needs: 5 phlebotomy chairs; Centrifuge (purchased by BCH). Purchase of this equipment will be delayed until we move to our permanent location in O'Connor. Blood draws for the initial recruitment will be done at Health Services.

Finalize space needs for recruitment activities by:

- Blood collection/processing: 02/28/2014
- Ht/Wt/BP measures: 03/03/2014
- Group Informational Visits: 03/03/2014
- Private Screening Visits: 03/03/2014 (through 5/2/14)

In an earlier discussion with Health Services it appears possible that the required blood draw for the initial screening can be done at Health Services. This would mean the phlebotomy chairs and possibly the centrifuge would only be required for the Assessment period.

Assessment Phase (to begin 8/1/14* through balance of study 5/16):

Space needs are required to conduct 4 assessments periods throughout each of the (two) nine-month study cohorts (September through May 2014/15 and then again September through May 2015/16). Each assessment period will last for two weeks; assessments are approximately 12 weeks apart. Equipment will be purchased (by BCH) and will need to remain in place throughout the entire grant project. During each assessment period there will be a flurry of activity.

O'Connor G31, the large lounge space on the ground floor will be used for this phase; however, it will only be enough space for the blood draws and phlebotomy chairs and bikes (see notes above and below). We suggest the additional space of G28 to be used for Oral Glucose Tolerance Tests, etc. and one additional office space for meetings and recruitment.

* Delivery of equipment begins after July 4th

- 5 beds
- 5 metabolic carts
- Phlebotomy chairs (same as above)
- Restroom facilities
- Exercise bikes
- Sink and water (ability to wash and sanitize equipment)
- Under counter refrigerator/freezer: -80 degrees with lock
- Centrifuge (same as above)
- Specimen refrigerator
- Food Refrigerator for snacks and doubly labeled water** (standard circuitry; regular voltage; similar to dorm refrigerator)
- Chairs to meet clients/discuss progress

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- Hand wash and Eye wash station (maybe other OSHA requirements?)
After reviewing the space we suggest G20 be turned in to the lab for blood draws and centrifuge. It will require a handwash and eye wash station; this is adjacent to the restroom and will likely make plumbing requirements a little easier.

**Doubly labeled water must be measured in safe environment; recommend Dining Services kitchen after hours and then delivered to Assessment site.

The centrifuge will be a table-top model, but because of the compressor to adjust the temperature, it weighs 200+ pounds. Once we have the centrifuge delivered and balanced by the supplier, we will not want to move it.

Check In Area (to begin 9/1/14)

An area where we can talk briefly with participants on a daily basis (morning) and measure body weight. We are hoping to do check-ins at a place that is not too far away from the dining hall, possibly at the Campus Center. This can be a relatively small space but large enough to hold a scale (and be secured during the rest of the day). It must also be close to a bathroom.

Discussion with Maureen Fowler indicates a small “closet like” space could be made available at the Campus Center.

II. Occupancy Needs (days of the week, hours of the day)

Office Phase: Full-time usage to begin asap (no later than February 24th) and continue throughout the duration of the study (June, 2016). Space would not be utilized full-time during June and July of 2014.

Recruitment Phase: To begin 3/3/14 through 5/15/14 and then again spring of 2015 (January through May).

Assessment Phase: Beginning August 1, 2014, 2 week intervals every 12 weeks for the duration of the study (not over the summers).

At any given time, we could be doing various measurements on around 10 participants simultaneously. Quantification of the assessment periods: the numbers are substantial (e.g. 12-15 Resting Energy Expenditure (REE) measurements per day; at least 5 bike tests per day; at least 5 Oral Glucose Tolerance Tests (OGTT) per day; etc.). Knowing this, we will need to run multiple stations in parallel (e.g. stagger 12-15 REE's throughout the morning along with 5 OGTTs). Mornings will be the busiest since the REE's and OGTTs must be completed after an over-night fast. Since the 5 metabolic carts will be used all morning for the REE measures, we will need to schedule the bike tests in the afternoon/evening. Everything should be on wheels so we can roll the beds off to the side, bring in the bikes and hook them up to the metabolic carts.

It is critical that the space selected for the Assessment area have a back-up power source. In the event the building or the campus loses power, the freezers and refrigerators must maintain temperatures, so that we do not run the risk of compromising the study samples.

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BCH is in the process of looking into a temperature monitoring system for the freezer. The monitoring system will require a redundant power source and access to the Internet (WiFi or T1 line).

III. Telephone, Data, Card Access and Security Needs

All space will require security card access.

Phones—minimum of 4 telephones for office home; at least one phone access for Assessment site

Data—wireless access

As noted above a back-up power and monitoring source are required.

Security: locked office space; locked file cabinets; locked assessment space; locks on refrigerator. As of August, 2014 the door to O'Connor will require a doorbell for evening and weekend access. Throughout the study assessments will take place on some evenings and weekends.

IV. Plumbing Needs

The assessment space requires a sink with running water /hot water as well as water for an eye wash station. Some equipment will need to be sterilized.

V. Air Conditioning Needs

Ideally a temperature control will be available for the Assessment space (to control for the REE tests).

VII. Bio-hazards and Waste Needs/Protocols

Medical waste will require a separate closet space for storage. Bio-hazard pick-up can likely be combined with Health Services (separate billing to BCH).

Emergency response protocols and on call nurses during the Assessment periods will be required.