

May 2, 2014

Patricia K. Luoto, EdD, RD
Project Director, Framingham State Food Study (FS)²
Professor Emeritus, Food and Nutrition
Framingham State University
100 State Street
Framingham, MA 01701

Dear Dr. Luoto,

Thank you for informing us of the tax liability issue, raised by your Business Office, regarding provision of the test diets to participants employed at FSU. We recognize the importance of this issue and want to make sure we find the right course of action for everyone involved.

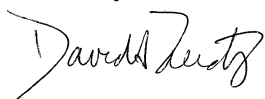
Certainly, any form of compensation in exchange for work or effort is taxable according to the law. The stipends provided to participants clearly fall within this category, and we so inform any student, faculty, or staff interested in the study.

However, the study diets fall into a different category, because participants are required to eat them in a strictly prescribed fashion, as an inherent aspect of the study design. For purposes of comparison, consider other more common types of clinical research, in which participants may be given expensive drugs or devices (e.g., a \$10,000 heart valve), or costly exercise equipment for long-term home use. In none of these situations is the provision of valuable items or services considered taxable. Were the IRS to make such a determination, most sophisticated clinical research would grind to a halt. For nutrition research, food is the "drug" under study. Indeed, in our 15 years of running feeding studies, we have never considered study diets as compensation, nor heard of any other investigator in the US doing so.

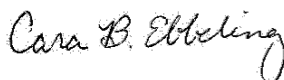
Thus, we do not believe that provision of the mandatory diets to non-resident student, faculty, or staff participants constitutes taxable compensation. Moreover, we also propose that the component of the cash payment to students for the meal plan be considered "reimbursement" for required study expenses, providing consistency among all participants, as described on the following page. Such a policy ensures that participants do not incur a tax liability for mandatory components of the study, about which they have no choice due to the randomized design of the study.

Thank you for carefully considering this issue with your Business Office. We look forward to successful implementation of a landmark study.

Sincerely,



David S. Ludwig, MD, PhD
Principal Investigator
Framingham State Food Study



Cara B. Ebbeling, PhD
Principal Investigator
Framingham State Food Study



Gloria L. Klein, MS, RD
Study Director
Framingham State Food Study

Reimbursement (non-taxable) and Compensation (taxable) for Study Participants

| Week | Phase or Event | Resident Students | | | Non-Resident Students, Faculty, Staff | |
|------|----------------|---------------------|-------------------|----------------------|---------------------------------------|----------------------|
| | | Monthly Meal Plan * | Monthly Stipend * | Additional Stipend † | Monthly Stipend * | Additional Stipend † |
| | | Reimbursement | Compensation | | Compensation | |
| -9 | Run-In | \$400 | \$100 | \$200 | \$100 | \$200 |
| -4 | Run-In | \$400 | \$120 | | \$120 | |
| 1 | Test | \$400 | \$120 | \$300 | \$120 | \$300 |
| 6 | Test | \$400 | \$130 | | \$130 | |
| 11 | Test | \$400 | \$140 | \$400 | \$140 | \$400 |
| 16 | Test | \$400 | \$150 | | \$150 | |
| 21 | Ad libitum | \$400 | \$170 | \$400 | \$170 | \$400 |
| | Completion | \$420 | \$550 | \$500 | \$550 | \$500 |

* We propose monthly payments for participating in the intervention. Each payment includes reimbursement for the meal plan (resident students only) and a stipend as compensation for time and effort to adhere to the study diets.

† We propose an additional stipend as compensation for time and effort required for measurement of study outcomes at specified time points.