Section on Protection of Human Subjects (this Human Subjects Research meets the definition of non- exempt Human Subjects Research)

PROTECTION OF HUMAN SUBJECTS

Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

- x Justifica tion: Human subject data during weight loss a requirement to validate the predictive power of the mathematical model to estimate energy intake during caloric restriction. In addition, determining what characteristics lead to larger percentages of compliance to diets requires human subject data with a broad set of markers such as demographic, psychological, and health characteristics during weight loss. In addition, many subjects cycle between positive and negative energy balance during weight loss. Data is required for accurate parameter estimation during weight cycling.
- x Characteristics of population:

Study(Name and location)	Male (N)	Female (N)	Age (yrs)	Height (cm)	Baseline Weight (kg)	Race W=White	R (al)14 Bg.n

						criteria for this study.
Westerterp Weight Loss Data Maastrich University Medical Centre, The Netherlands	54	10	36.6±2.3	170.1±5.4	88.3±1.3	100%W
Racette University of Wisconsin-Madison		13	39.4±5.2	164.6±5.7	90.6±9.6	100%W
Levine Overfeeding Mayo Clinic	10	12	38.1±7.8	170.2±8.1	82.9±19.6	100%W

Kiel

Christian-
Albrechts-Si]9 0al4 0sP 2 re f*3BT3/9 Tw 11.0ht 97( )Tc -ET.C 0.BT3/LBody 1 Tf 11.153 Tw 1.63

The
Comprehensive
Assesment of
Long-Term Effects
of Reducing

	period x Measurements of resting metabolic rate during weight gain period x Target energy intake designated by study
Christian-Albrechts-University, Kiel, Germany	x Resting metabolic rate x Physical Activity x Bi-weekly body mass x Age and height at baseline x Body composition during weight cycling

- x Researchers who have access to individually identifiable private information: The key investigator at the study site is the only researcher with access to individually identifiable private information about the human subjects.
- x Data management on site: All data collected at a site is managed by a office of data management and needs to be requested by the key investigator at the site.

c. Potential Risks

- x It is possible that when the model energy intake estimates indicate non-adherence to dietary protocols the revelation may be distressing to subjects who participated in the study and learn of the results through published material. The level of discomfort will be hard to measure unless a subject from the study contacts the site on their own.

Adequacy of Protection Against Risks

a. Recruitment and Informed Conse nt

Informed Consent: All subjects in the studies we are examining provided informed consent which was reviewed by governing IRB except for the Westerterp studies and the Kiel study. The Westerterp studies conformed to the standards set by the Declaration of Helsinki, obtained

subject study data we are using required large amounts of participant time and effort to collect approximate measures of energy intake. The benefit of alleviating intense data collection for future weight loss subjects outweighs the risk of discomfort from knowledge of true adherence to diets.

Inclusion of Women and Minorities

The CALERIE Phase I and Levine Overfeeding studies include approximately 50% representation by each gender. We do not at this time have the distribution of gender in the Merck database. We require representation by both genders to determine conclusions based on model results.

A. ***One gender:***

The Racette study, Kiel study, and portions of the Westerterp studies were collected using one gender only.

B. ***Minority groups or subgroups:***

Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study. We compensate for the lack of diversity in a single study by pooling data from several studies which includes a broad set of minority groups. We are seeking sources of data that are diversified by race as they provide more validation for the model and more markers of possible correlations to adherence.