

## **Proposed Measures & Variables:**

### **Primary Outcome: Dietary Variables**

The primary dependent variable is dietary consumption of F & V, with other dietary variables as secondary outcomes. Given the complexity of dietary assessment we will use multiple dietary measures including:

**Block Food Frequency Questionnaire:** The Block Food Frequency Questionnaire (FFQ) is a comprehensive measure of dietary intake. It is eight pages and queries 106 foods. It asks usual portion size as “small,” “medium,” or “large,” providing reference medium portion sizes. In addition, it includes questions on dietary supplements, restaurant eating, fat and use of low-fat foods. Summary questions and several demographic/health-related questions are also included in the FFQ.[Subar, 2001 #59] Block Food Frequency Questionnaires will be purchased from and analyzed by Berkeley Nutrition Services, Berkeley, CA. The food list and the nutrient values to be associated with it were developed using dietary data from 11,658 adult respondents to the Second National Health and Nutrition Examination Survey (NHANES II). Portion sizes to be associated with each food item were derived from observed portion size distributions in NHANES II, based on three-dimensional models. [Block, 1986 #125]

**NIH/NCI Fruit and Vegetable Scan:** Servings of F&V will be assessed using the NIH/NCI Fruit and Vegetable Screener (FVS). [Thompson, 2000 #33] Ten items are used to assess portion size and servings of F&V. The FVS was found to closely approximate estimated median intakes of fruits and vegetables compared to 24-hour dietary recall data and correlation coefficients ranged from .56 - .59.

In addition, two procedures applied to a sub-sample will be used to validate and calibrate these self report measures: 24 hour recalls and blood carotenoids levels.

**Plasma Carotenoids:** As an objective biological measure of F&V intake, blood will be collected and analyzed for a random 50% sample for plasma carotenoids at T<sub>12</sub>. Bloods will be collected after a fast of at least 6 hours and protected from light throughout processing. Plasma will be stored at -70 deg C until analysis by a high-performance liquid chromatography method that will be used to measure concentrations of alpha-carotene, beta-carotene, lycopene, lutein, zeaxanthin, and beta-cryptoxanthin. Kristal et al. [Kristal, 2000 #149] found that the correlation between the 24 hour recall measures of total F&V and plasma carotenoids was slightly higher than correlations for food frequency questionnaires. In addition, LeMarchand et al. [Le Marchand, 1994 #115] found a 29% rise in total plasma carotenoid levels occurred with a significant increase in F&V intake. His data also showed that change in total plasma carotenoids correlated well ( $r=.7$ ) with the overall change in F&V intake. The correlation was thought to be an adequate marker for adherence at the group level. [Greenwald, 1992 #30]

**24-Hour Dietary Recall:** To assess the validity of the dietary measures used in this study, three unannounced 24-hour Dietary Recalls will be administered over the telephone to 50 men and 50 women randomly selected at baseline (T<sub>0</sub>). The 24-hr recall is a validated method of measuring dietary behavior and the nutrient composition of the diet. Each selected subject will be mailed a set of two-dimensional food visuals which allow subjects to describe portion sizes of different types of foods. They will be asked to refer to these visuals during the telephone interviews. The recall consists of a complete audit of what foods the person consumed during the previous 24 hours. For each type of food reported, the interviewer will note the amount consumed including portion size. The elapsed time between the first and the third interview will be no more than 14 days in order to minimize the possibility of change in dietary behavior. Each interview is expected to take approximately 20 minutes.

The data from the three recalls will be analyzed using the University of Minnesota NDS database. Foods reported will be assigned to four food groups: F&V, whole-fat dairy products, whole grains, and red/processed meat. Frequency of consumption of foods in the groups will be determined using portion size criteria based on the American Dietetic Association (ADA) Exchange Lists[ADA, 1989 #92] and the

USDA's Food Guide Pyramid.[USDA, 1992 #93] The nutrient intake variables (e.g., percent calories from saturate fat, etc.) will be constructed using the NDS protocols.

### **Secondary Dietary Outcomes**

Global Diet Index (or Overall Diet Indices): An overall picture of diet quality will be assessed using a method of scoring based on specified dietary intakes called the Global Diet Index (GDI). The method is a modification of the widely disseminated Healthy Eating Index. [Delichatsios, 2001 #1] Overall diet quality will be computed using data from the Block FFQ. Each subject will be assigned a score from 0 (worst) to 100 (best) for intake of each of five food groups (see Appendix A). Cutoffs for each food group are based on published guidelines,[NCI, 2001 #106; USDA, 1992 #93] expert opinion, and the frequency distributions of these food groups in the original TLC-EAT study population. [Delichatsios, 2001 #1]

### **Potential Mediators of Intervention Effects**

Goal System Variables: As one of the intervention is testing an innovative approach to maintenance of behavior change based on goal systems theory, we are measuring a number of attributes of this theory. Data from these measures will be analyzed as mediating variables of intervention effects as well as used to individualize the TLC-EAT-GM intervention content. Variables include:

Goal Systems Assessment Battery Variables: The Goal Systems Assessment Battery (GSAB) [Karoly, 1995 #69] is a comprehensive, multi-factor instrument with good psychometric properties[Karoly, 1995 #69; Karoly, 1996 #145] that assesses nine aspects of self-conscious goal pursuit, each with 4-items scales. These nine variables are conceptually organized into four goal related questionnaires. The Directive Function Questionnaire assesses goal-related value and self-efficacy. The Regulatory Function Questionnaire assesses goal monitoring ("I keep track of my overall progress towards this goal") and social comparison ("I evaluate my progress towards this goal by comparing myself to people who are very much like me in terms of background and ability"). The Control Function Questionnaire consists of three subscales that assess planning ("I plan in advance..."), self-criticism ("I criticize.."), and self-reward ("I reward..."). The final function, measured with the Arousal Function Questionnaire, assesses the emotional result of goal pursuit with a positive arousal scale ("Working on this goal makes me happy") and a negative arousal scale ("Thinking about this goal gives me uneasy feeling").

Goal Effort: A 5-item sub-scale of the Intrinsic Motivation Inventory will be used to assess effort expended on a goal. Examples of items on the effort scale are "I didn't put much energy into this." and "I tried very hard on this activity."

Non-Dietary Goals Identification: The TLC-EAT.GM intervention is based on the premise that if this intervention assists individuals in effectively managing the demands of the multiple goals in their lives, their newly acquired healthy dietary behaviors will be protected and maintained (see Section B.8). To evaluate this hypothesis a number of major dimensions of goal systems will be measured including the specific non-dietary goals themselves. During the baseline survey of the maintenance study (T<sub>0</sub>) subjects will be asked to report their five most important currently active non-dietary personal goals. Currently active goals will be elicited by asking for goals that they think about or work on some days every week. This description will help elicit goals that are of a similar level of specificity as dietary goals. The interviewer will be trained to redirecting the subject if a goal is too specific (e.g., I want to play golf more this week) or too general (e.g., I want to be a good person). The interviewer will also establish with the subject a short label that will identify each goal for the subject. This label will be used in future questions and, depending on group assignment, in the TLC-EAT.GM conversations. Although some subjects might not have 5 identifiable goals, we expect this should be a minority of subjects and not substantially affect the measurement or intervention activities.

Goal Interrelatedness: We will also assess a set of variables which will characterize the relationships between the subject's dietary goals and each of their non-dietary goals. Inter-goal facilitation, inter-goal conflict, and inter-goal redundancy will be assessed using a modified version of Emmons and King's[Emmons, 1988 #68] Goal Conflict measure. For each non-dietary goal, subjects will be asked to

what degree this goal promotes their dietary goal, is redundant or substitutive with their dietary goal, or conflicts with their dietary goal.

**Resource Allocation for Goals:** There is no established battery of tests to measure resources available for goal pursuit, which is hypothesized to be an important predictor of goal success. The resources available for pursuing a goal will be quantified by assessing three types of resources: (1) SES, (2) social support, and (3) time availability. Socioeconomic status measures will be obtained from demographic questions and will include income, perceived levels of discretionary income[Rakowski, 1998 #200] and extended family economic resources. Time allotment will be assessed by employment status, number in household, role in household (primary food shopper, preparer, caretaking hours), community or professional group meetings to attend, and perceived number of hours available for discretionary use. [Kumanyika, 2000 #22]

### **Other Mediating Variables:**

**Social Support:** Perceived social support for dietary behavior will be assessed with a modification of the Scales to Measure Social Support for Diet and Exercise[Sallis, 1987 #72] by keeping just the dietary items. This measure has been demonstrated to be reliable.

**Self Efficacy:** Given the importance of self-efficacy for behavior initiation and persistency, another measure of self-efficacy designed specifically for dietary behaviors will be included. We will measure self-efficacy of consuming goal levels (e.g., servings) of foods most related to the dietary regimen goals of this study: fruits and vegetables, foods high in saturated fat (red and processed meat, and whole fat dairy), and whole grains. Self-efficacy will be assessed with a 10-item scale ( $\alpha = .90$ ) based on the work of Sallis[Sallis, 1988 #70] and others. [Sheeska, 1993 #71] Sample items include: how confident are you that you could order fruits and vegetables when eating at a restaurant? And, how confident are you that you could eat healthy foods like fruits and vegetables when you are depressed or in a bad mood? Items are answered on a three-point continuum ranging from “not at all confident” to “very confident.”

### **Other Variables:**

The personal attributes assessed and evaluated as potential confounding variables not included above include: (a) additional sociodemographic information, (b) health status and co-morbidity, (c) depression and anxiety, (d) season intervention occurs, and (e) dietary history and concurrent interventions.